		MA.	Advets review	Frent Keporti UL Information		stem (A ERS) Report				
Date: 12/07/1989	ISR Number: 624636-9	Report Type: Direct		Company Report Numbe	r:		Age: 16 YR	Com	der: Male	
Outcome	_ PT	Report Source	Product					Gai	uer: Male	
Hospitalization -	Bipolar I Disorder	Consumer			Role	Manufacturer	Route	Dose/Unit	Duration	
Initial or Prolonged	Central Nervous System Depression Nos Depression Nec	·	Accutane		PS	Roche	ORAL		14 .	
Date: 12/12/1989	ISR Number: 625269-0	Report Type: Direct		Company Report Number	r;		Age:	Gen	der: Male	
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	.			
Hospitalization - Initial or Prolonged	Dermatitis Exfoliative Nos	Consumer	Accutane		PS	Roche	Route	Dose/Unit	Duration	
nual or Froinged	Dry Skin Gingivitis		_			ROCHE			854	
	Impotence									
Date: 11/20/1989						·			*	
Date: 11/20/1989	ISR Number: 626413-1	Report Type: Direct		Company Report Number	r;		Age: 18 YR	Gen	der: Male	_
Outcome	PT	Report Source	Product						IVIAIC	
	Chest Pain	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
	Muscle Spasms		Acculate		PS	Roche	ORAL		32	
	Neck Pain									
	Palpitations									
Date: 12/19/1989	ISR Number: 632208-5	Report Type: Expedited (15-Day)	Company Report Number	r: 890500	081001	Age: 20 YR	Can	der: Female	
Outcome	PT	Report Source	Product				g 201K	Gui	der: Female	•
Hospitalization -	Suicide Attempt	Foreign			Role	Manufacturer	Route	Dose/Unit	Duration	
Initial or Prolonged		Health Professional	Rosccutane		PS	Roche	ORAL		1	
Date: 02/22/1990	ISR Number: 642098-2									
	10th 11th 1967; 042098-2	Report Type: Expedited (15-Day)	Company Report Number	900200	122001	Age: 16 YR	Gen	der: Unknown	
Outcome	PT	Report Source	Product		Role	Manufacturer	P4			
Death	Anorexia	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration	
	Depression Nec				10	ROCEE	ORAL		60	
	Sedation Suicide Attempt									
Date: 02/23/1990	ISR Number: 644420-X	Report Type: Expedited (15-Day)	Company Report Number	900100	010001	Age: 19 YR	Gen		
Outcome	PT	Report Source	D				uge 19 IK	Gen	der: Male	
Other	Amnesia Nec	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Coma Nec	realiti Professional	Roaccutane		PS	Roche	ORAL	,	579	
	Sweating Increased									

				di lutornai					
Date: 03/14/1990	ISR Number: 646860-1	Report Type: Expedited	(15-Day)	Company Report P	lumber: 900200	228001	Age: 17 YR	Ger	ıder: Female
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Bipolar I Disorder Emotional Disturbance Nos	Study	Accutane		PS	Roche	ORAL	DUSECHIL	
	Suicide Attempt	Health Professional	Duricef		C	TOTAL .	UKAL		42
			Doxycycline		c				
Date: 03/01/1990	ISR Number: 647435-0	Report Type: Expedited	(15-Day)	Company Report N		020001	Age: 19 YR		
Outcome	PT	Report Source	Dundana			020001	Age: 19 1 K	Ger	ıder: Male
Hospitalization -	Paranoia	Foreign	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Personality Disorder Nos	Health Professional	Roaccutane		PS	Roche	ORAL		2
	Psychotic Disorder Nos			<u> </u>					
Date: 04/04/1990	ISR Number: 657492-3	Report Type: Direct		Company Report N	umber; PDR		Age: 16 YR	Ger	ıder: Male
Outcome	PT	Report Source	Product		Role	Manufacture.			
Hospitalization - Initial or Prolonged	Drug Interaction Nos	Health Professional	Accutane		PS	Manufacturer Roche	Route	Dose/Unit	Duration
mual of Protonged	Dystonia Paranoia		Retin-A		rs C	Rocne	ORAL		17
	Psychotic Disorder Nos		Tetracycline	4	c				
Date: 06/11/1990	ISR Number: 667406-8	Report Type: Periodic		Company Pay 43		751001			
Outcome	PT	·		Company Report N	umper: 890200	/31001	Age: 19 YR	Ger	nder: Female
Other	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Accutane		PS	Roche	ORAL.		136
Date: 06/11/1990	ISR Number: 667419-6	Report Type: Periodic		Company Report N	umber: 890200	594001	Age: 24 YR		
Outcome	PT	Report Source	Product				Age. 24 1K	Ger	ider: Male
	Amnesia Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Anxiety Nec	A TOTOGOTOTIAI			PS	Roche	ORAL		1119
	Insomnia Nec		Tagamet		С				
	Thinking Abnormal Nec	· · · · · · · · · · · · · · · · · · ·							
Date: 06/11/1990	ISR Number: 667547-5	Report Type: Periodic		Company Report N	umber: 8902012	223001	Age: 26 YR	Gen	nder: Female
Outcome	PT	Report Source	Product		D-I-	M	_		
Other	Anorexia	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
	Anxiety Nec				rə	Roche	ORAL		123
Date: 06/11/1990	ISR Number: 667562-1	Report Type: Periodic		Company Report N	umber: 8902011	105001	Age: 21 YR	Gen	ıder: Male
Outcome	PT	Report Source	Product		D-1-	25	-		1,111
	Depression Nec	Consumer						Dose/Unit	Duration
	Depression Nec Dyspnoea Nos		Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	

Date: 06/11/1990	ISR Number: 667577-3	Report Type: Periodic		Company Report Number: 900	2000	076001	Age:	35 YR	- Cim	der: Male
Outcome	PT	Report Source	Product							
Other	Delusion Nos Depression Nec	Health Professional	Accutane	Role PS	<u>.</u>	Manufacturer Roche	Rou ORA		Dose/Unit	Duration
Date: 06/11/1990	ISR Number: 667588-8	Report Type: Periodic		Company Report Number: 900	2002	256001	Age:	28 YR	Gen	der: Female
Outcome	PT	Report Source	Product	Role		Manufautuum				-
	Diarrhoea Nos	Health Professional	Accutane	PS	_	Manufacturer Roche	Rou		Dose/Unit	Duration
	Dyspareunia Nec Gastric Ulcer		Bactrim Ds			Roche	ORA	ıL .		90
-	Rectal Disorder Nos									
Date: 06/11/1990	ISR Number: 667605-5.	Report Type: Periodic		Company Report Number: 900	2002	280001	Age:		Gen	der: Female
Outcome	PT	Report Source	Product	-						ин. гелые
	Amenorrhoea Nos	Consumer	Accutane	Role PS		Manufacturer	Rou		Dose/Unit	Duration
	Depression Nec Dry Skin		Lo/Ovral	C		Roche	ORA	L		243
	Epistaxis									
Date: 06/11/1990	ISR Number: 667616-X	Report Type: Periodic		Company Report Number: 900	2002	138001	Age:	16 YR	Gene	der: Male
Outcome	PT.	Report Source	Product	Role		Manufacturer	Rou		D #1 #	
Other	Emotional Disturbance Nos Personality Disorder Nos	Health Professional	Accutane	PS	_	Roche	ORA		Dose/Unit	Duration
Date: 06/11/1990							OKA	<u>. </u>		32
	ISR Number: 667621-3	Report Type: Periodic		Company Report Number: 900	2002	12001	Age:	28 YR	Gene	der: Male
Outcome Other	PIIP-1 of T	Report Source	Product	Role	•	Manufacturer	Rou	te	Dose/Unit	Duration
Uther	Blood Prolactin Increased Impotence	Health Professional	Accutane	PS	-	Roche	ORA		Dose Olli	177
	Lymphadenopathy		Zovirax	c			Olu	u.,		1//
Date: 06/11/1990	ISR Number: 667624-9	Report Type: Periodic								
Outcome		·-		Company Report Number: 900	2002	00001	Age:	38 YR	Gene	der: Male
Other	PT Impotence	Report Source	Product	Role	:	Manufacturer	Rou	te	Dose/Unit	Duration
~ · · · · · · · · · · · · · · · · · · ·		Health Professional	Accutane	PS	_	Roche	ORA			210
Date: 06/11/1990	ISR Number: 667633-X	Report Type: Periodic		Company Report Number: 900	2000	72001		16 YR	Gene	ler: Male
Outcome	PT	Report Source	Product	Role		Manufacturer	Rout			
Other	Anorexia Hostility	Health Professional	Accutane	PS	-	Roche	ORA		Dose/Unit	Duration
	Personality Disorder Nos Sedation		Tegretol	Ĉ			UKA	L		138

		1	Redom	r Event Report Of Information		Report			
Date: 06/11/1990	ISR Number: 667741-3	Report Type: Periodic		Company Report Numb	er: 890200)474001	Age: 32 YR	Gen	ıder: Female
Outcome	PT	Report Source	Product		D.i.	Manufacturer			- Lamago
Other	Dry Eye Nec	Health Professional	Accutane		Role PS	Roche	Route	Dose/Unit	Duration
	Libido Decreased Photosensitivity Reaction Nos				го	Kocne	ORAL		112
	Vulvovaginal Disorder Nos								
Date: 06/11/1990	ISR Number: 667751-6	Report Type: Periodic							
Outcome	PT	report Type: Penodic		Company Report Numb	er: 890200	0522003	Age: 19 YR	Gen	ider: Male
Other	Emotional Disturbance Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Oute	Personality Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL		5
Date: 06/11/1990	ISR Number: 667771-1								
		Report Type: Periodic		Company Report Numb	er: 890200	0581002	Age: 16 YR	Gen	ider: Male
Outcome	PT PT	Report Source	Product		Role	Manufacturer	Route	D	~ "
Other	Blood Lactate Dehydrogenase Increased	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration
	Hostility						OKAL		36
	Personality Disorder Nos								
Date: 06/11/1990	ISR Number: 667772-3	Report Type: Periodic		Company Report Numb	n= 800200	581001	A 4677		
Outcome	PT	Report Source	.	and and ambout themes	. 070200	201001	Age: 16 YR	Gen	der: Male
Other	Hostility	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Personality Disorder Nos	Ticular i Torcasiojaji	Accutane		PS	Roche	ORAL		146
Date: 05/23/1990	ISR Number: 667906-0	Report Type: Expedited (15 Day)						
Outcome	PT .		13-Day)	Company Report Number	er: 900200	423001	Age: 17 YR	Gen	der: Male
Death	Amnesia Nec	Report Source	Product	·	Role	Manufacturer	Route	Dose/Unit	Duration
	Arthythmia Nos	Health Professional	Accutane		PS	Roche	ORAL		93
	Dry Skin								,,,
	Stupor								
Date: 06/11/1990	ISR Number: 667960-6	Report Type: Periodic		Company Report Number	800701	083001	· · · · · · · · · · · · · · · · · · ·		
Dutcome	PT	D	_	company report remine	1: 0902010	003001	Age: 31 YR	Gen	der: Male
Other	Condition Aggravated	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Hyperthyroidism	Health Professional	Accutane		PS	Roche	ORAL	·	143
	Nezvousness								
	Tachycardia Nos								

Date: 06/11/1990	TOTAL STATE OF THE		38833000	Of Information		Hepert				
1	ISR Number: 667990-4	Report Type: Periodic		Company Report Num!	er: 89020	0884001	Age: 16 YR			********
Outcome	PT	Report Source	Product				Age: 16 YR	Gen	nder: Male	
Other	Amnesia Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
Date: 06/11/1990	Top as		Acculation		PS	Roche	ORAL			
	ISR Number: 668366-6	Report Type: Periodic		Company Report Numb	er- 900200	0135001				
Outcome	PT	Report Source	Dandard			7155001	Age: 35 YR	Gen	ıder: Male	
Other	Depression Nec	Health Professional	Product Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
			Aventyl		PS	Roche	ORAL		17	
			Antabuse		С					
			Tranzene		С					
Date: 06/11/1990	ISR Number: 668397-6		TallAcile		С					
Outcome		Report Type: Periodic		Company Report Numb	er: 890200	997001	Age: 29 YR			
Other	PT P	Report Source	Product		ъ.,			Gen	der: Female	
Other	Depression Nec	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration	
Date: 06/11/1990	ISR Number: 668407-6				PS	Roche	ORAL		2	
		Report Type: Periodic		Company Report Numb	er: 900200	383001	Age: 17 YR			
Outcome Other	_ PT	Report Source	Product				Age: 1/ YR	Gen	der: Female	
Other	Agitation Epistaxis	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
	Myalgia		· woodanic		PS	Roche	ORAL		23	
Date: 06/11/1990			·							•
	ISR Number: 668835-9	Report Type: Periodic		Company Report Number	890200	630001				
Outcome	PT	Report Source	Dendered		0,0200	037001	Age: 19 YR	Gene	der: Female	
Other	Confusion	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Grand Mal Convulsion		Accutane		PS	Roche	ORAL		140	
	Muscle Twitching Syncope									
ate: 06/11/1990										
	ISR Number: 668841-4	Report Type: Periodic		Company Report Number	r: 890200s	354001				
Outcome	PT	Report Source	Product		*, 0,02000	554001	Age: 20 YR	Gend	ier: Female	
Other	Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
ate: 06/11/1990			Acculance		PS	Roche	ORAL		4	
ate; 00/11/1990	ISR Number: 668849-9	Report Type: Periodic		Company Report Numbe	9000011					
utcome	PT	Report Source			r; a902010	12008	Age:	Gend	ler: Female	
	Blindness Night	Study	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Headache Nos	Health Professional	Accutane		PS	Roche	ORAL		3	
	Insomnia Nec	I TOLUMBURAL							3	

Date: 06/11/1990	ISR Number: 668850-5	Report Type: Periodic		Company Report Numb					
Ontcome	PT	Report Source		company Report 14mili	er: 890201	1012011	Age:	Ger	nder: Female
	Amblyopia Nos	Study	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Candida Nos Dermatitis Nos	Health Professional	Accutane Elavil		PS	Roche	ORAL		
	Emotional Disturbance Nos		CIRAII		С				
Date: 06/11/1990									
	ISR Number: 668859-1	Report Type: Periodic		Company Report Numb	er: 900200	0338001	Age:		
Outcome	<u>PT</u>	Report Source	Product	· · ·			Age:	Gen	nder: Female
	Emotional Disturbance Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
D. a. Ochana	Thinking Abnormal Nec		- recotant		PS	Roche	ORAL		
Date: 06/11/1990	ISR Number: 668874-8	Report Type: Periodic		Company Report Numb					
Outcome	<u>PT</u>	Report Source		company Report 14mm	er: 900200	1154001	Age: 26 YR	Gen	ider: Male
Other .	Alopecia	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
•	Depression Nec	THE PROPERTY IS A PROPERTY OF THE PROPERTY OF	Accutane		PS	Roche	ORAL		64
	Emotional Disturbance Nos Infection Nos								
Date: 06/11/1990									
	ISR Number: 668878-5	Report Type: Periodic		Company Report Number	er: 890200	740001			
Outcome	PT	_ Report Source	Product			740001	Age: 18 YR	Gen	der: Male
Hospitalization - Initial or Prolonged	Hostility	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
of Francisco	Insomnia Nec Personality Disorder Nos		Tetracycline		PS	Roche	ORAL		24
Date: 06/11/1990			Totalycinie		С .				
	ISR Number: 668879-7	Report Type: Periodic		Company Report Number	800200	121001			
Outcome	<u>PT</u>	Report Source	D 3	1	1. 0902004	+31001	Age: 44 YR	Gene	der: Male
Other	Aspartate Aminotransferase Increased	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Gamma-Glutamyltransferase		Accutane Alcohol		PS	Roche	ORAL		1
	Increased		AICOLOL		С				-
	Non-Accidental Overdose Suicide Attempt								
ate: 06/11/1990									
	ISR Number: 668903-1	Report Type: Periodic		Company Report Numbe	r: 8902010	339001			
utcome	PT	Report Source	Product				Age:	Gend	ier: Male
ther	Emotional Disturbance Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Hyperkinetic Syndrome		Accurane		PS	Roche	ORAL		
•									
				,					
08/03/2000									

	SR Number: 668912-2	Report Type: Periodic	٠.	Company Report Numbe	r: 890200	373001	Age: 27 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Amnesia Nec Depression Nec	Health Professional	Accutane		PS	Roche	ORAL	. Doso ont	97
	Photosensitivity Reaction Nos Skin Discolouration						·		
	R Number: 671863-0	Report Type: Periodic	_	Company Report Numbe	r: 8902000	036001	Age: 50 YR	Gen	ıder: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	D	
Other	Impotence	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration 147
	R Number: 671872-1	Report Type: Periodic		Company Report Numbe	r: 8902000	023001	Age: 16 YR	Gen	der: Female
Outcome	PT Asthenia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane		PS	Roche	ORAL		508
Date: 07/06/1990 IS	R Number: 671909-X	Report Type: Periodic		Company Report Number	 8802014	153001	Age: 15 YR	Gen	der: Male
Outcome	PT	Report Source	Product		D.1.		- ·		WELL INTALE
Other	Emotional Disturbance Nos	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
	Personality Disorder Nos				ra	Roche	ORAL		152
	R Number: 671927-1	Report Type: Periodic		Company Report Number	8902002	279001	Age: 31 YR	Gen	der: Female
Outcome	PT Alopecia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Omer	Eye Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL	- Dase Care	93
	Headache Nos		Peldene		С		O.L.		93
	Schizophrenia Nos								
Date: 07/06/1990 IS	R Number: 671929-5	Report Type: Periodic		Company Report Number	: 8902002	84001	Age: 20 YR	Gen	der: Female
Outcome	PT	Report Source	. Product		n	30		Jul	remaie
Other	Palpitations	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
Date: 07/06/1990 IS	R Number: 671933-7	Report Type: Periodic			PS	Roche	ORAL		140
Outcome	DT	· · · · · · · · · · · · · · · · · · ·		Company Report Number	: x902003	09001	Age: 14 YR	Gene	der: Female
Other	Aspartate Aminotransferase	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Ouna .	Increased	Health Professional	Accutane		PS	Roche	ORAL		35
	Depression Nec								
	Hepatic Function Abnormal Nos Hypocholesterolaemia								

		FDA	Advers	Dwent Reports		tom (ATERS)				
		I	0.000	Of Internation		Report				
Date: 07/06/1990	ISR Number: 671988-X	Report Type: Periodic		Company Report Numbe	er: 890200	187001	Age: 17 YR	Ger	ıder: Male	
Outcome	PT	Report Source	Product		Role	Manufacturer	.			
Hospitalization - Initial or Prolonged	Depression Nec	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration	
Date: 07/06/1990	ISR Number: 672126-X	Report Type: Periodic		Company Report Numbe	n= 880201	242001			140	
Outcome	PT	Demond Common			1.000201	242001	Age: 14 YR	Gen	ider: Female	
Other	Asthenia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Confusion	Health Professional	Accutane		PS	Roche	ORAL		15	
	Depression Nec									
	Myalgia									
Date: 07/06/1990	ISR Number: 672556-6	Report Type: Periodic		Company Report Numbe	r: 880201	425001	Age: 16 YR	Gen	ıder: Female	
Outcome	PT PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D	
Hospitalization - Initial or Prolonged Other	Depression Nec Suicide Attempt	Health Professional	Accutane		PS	Roche	ORAL	DOSE CHIL	Duration 113	
Date: 06/20/1990	ISR Number: 672873-X	Report Type: Expedited (15-Day)	Company Report Number	r: 900200	599001	Age: 17 YR	Gen	ıder: Male	
Outcome	PT .	Report Source	Product		Role	Manufacturer	Route	D #1-14	-	
Hospitalization - Initial or Prolonged	Delusion Nos Hallucination Nos	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration	
Other	Paranoia						OKAL		7	•
	Psychotic Disorder Nos									
Date: 06/20/1990	ISR Number: 672874-1	Report Type: Expedited (15 Dow	2 7				·		·
Outcome	PT	IVF ampointed (is-Day)	Company Report Number	r: 900200	597001	Age: 23 YR	Gen	der: Male	
Hospitalization -	Delusion Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
Initial or Prolonged	Personality Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL		47	
Other	Psychotic Disorder Nos		Tetracycline		C				,	
	Sleep Disorder Nos									
Date: 06/15/1990	ISR Number: 673050-9	Report Type: Expedited (1	15-Day)	Company Report Number	r: 900100	237001	Age:	Gen	der: Male	
Outcome	PT	Report Source	Product		Role	Manufacturer	Dant	Th #7 #		
Death	Depression Nec Insomnia Nec	Foreign	Roaccutane		PS	Roche	Route	Dose/Unit	Duration	
	Suicide Attempt	Health Professional				ACCUSE .	ORAL		54	
	Weight Decreased									

						Report			
Date: 06/26/1990	ISR Number: 675196-8	Report Type: Expedited	(15-Day)	Company Report Number	er: 890800	046001	Age:	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	* .		
Hospitalization - Initial or Prolonged	Asthenia Depression Nec Psychotic Disorder Nos	Foreign Health Professional	Roaccutane		PS	Roche	Route ORAL	Dose/Unit	Duration 103
Date: 07/19/1990	ISR Number: 682006-1	Report Type: Expedited	(15-Day)	Company Report Number	er: 900200	749001	Age: 24 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	T. 67	
Hospitalization - Initial or Prolonged	Hallucination Nos	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration
Other	Major Depressive Disorder Nos Psychotic Disorder Nos		Retin-A		C		OKAL		1 .
Date: 07/17/1990	ISR Number: 682387-9	Report Type: Expedited	[15-Day]	Company Report Number	er: 890315	726001	Age: 35 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Acute Circulatory Failure Amnesia Nec Syncope	Foreign Health Professional	Roaccutane		PS	Roche	ORAL	2000 0211	Duration
Date: 08/16/1990	ISR Number: 687204-9	Report Type: Expedited ((15-Day)	Company Report Numbe	r: 900316	487001	Age: 22 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Mannfacturer			112110
Disability	Cheilitis Conjunctivitis Nec Pain Nos Suicide Attempt	Poreign Health Professional	Roaccutane		PS	Roche	Route	Dose/Unit	Duration 451
Date: 09/27/1990	ISR Number: 692327-4	Report Type: Direct		Company Report Numbe	r: DEN27:	20	Age:	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	D4-		
	Alopecia Chromosomal Abnormality Nos	Consumer	Accutane		PS	Roche	Route	Dose/Unit	Duration 152
	Depression Nec Skin Discolouration		· 						
Date: 10/10/1990	ISR Number: 697260-X	Report Type: Direct		Company Report Number	r:		Age:	Gen	der: Female
Outcome	PT Alexada	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Alopecia Menometrorrhagia Pain Nos	Health Professional	Accutane Keflex		PS C	Roche			93
	Path Nos Palpitations			*	-				

Date: 01/16/1991	ISR Number: 716667-5	Report Type: Expedited (1	5-Day)	Company Report Numbe	r: 900201	460001	Age: 18 YR	Gen	der: Male	7.
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit		
Death .	Arthralgia Major Depressive Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL	Doservant	Duration 105	
Other	Myalgia Suicide Attempt						· ·			
Date: 03/25/1991	ISR Number: 736346-8	Report Type: Expedited (1	5-Day)	Company Report Number	r: 910200	256001	Age: 38 YR	Gen	der: Female	
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	D//		
Hospitalization - Initial or Prolonged Disability	Anxiety Nec Arthralgia Collagen Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration 76	
Other	Scleroderma									
Pate: 03/13/1991	ISR Number: 737374-9	Report Type: Expedited (1	5-Day)	Company Report Number	r: 9102002	279001	Age: 16 YR	Gen	der: Female	
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
Hospitalization - nitial or Prolonged	Amblyopia Nos Arthralgia Depression Nec	Consumer	Accutane		PS	Roche	ORAL	Doso Chit	123	
	Influenza Like Illness		<u> </u>							
Date: 04/09/1991	ISR Number: 741365-1	Report Type: Expedited (1:	5-Day)	Company Report Number	r: 9005002	246001	Age: 20 YR	Gen	der: Male	
Outcome Hospitalization -	PT Anxiety Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
nitial or Prolonged	Headache Nos Hydrocephalus Nos	Foreign Health Professional	Roaccutane		PS	Roche	ORAL		184	
Date: 04/12/1991	ISR Number: 741874-5	Report Type: Expedited (1:	5-Day)	Company Report Number	9101000	093001	Age: 19 YR	Gene	der: Malc	_
Outcome	PT	Report Source	Product		Role	Manufacturer	D -4			
Death	Arthralgia Cheilitis	Foreign	Roaccutane		PS	Roche	Route	Dose/Unit	Duration 173	
	Conjunctivitis Nec Suicide Attempt	Consumer					OMIL		1/3	
Date: 04/16/1991	ISR Number: 742951-5	Report Type: Direct		Company Report Number	:		Age: 18 YR	Gene	der: Male	
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D#	
Peath	Alopecia Blindness Night Depression Nec	Consumer	Accutane		PS	Roche	ORAL	DOSE CHR	Duration 105	
	Suicide Attempt									
08/03/2000										_

Date: 04/16/1991	ISR Number: 743620-8	Report Type: Direct	Company Rep	ort Number:	-	Age: 18 YR	Gender: Male
Outcome	PT	Report Source	Product				
Death	Depression Nec	Health Professional	Accutane	Role PS	Manufacturer Roche	Route	Dose/Unit Duration 98
Date: 04/02/1991	ISR Number: 745098-7	Report Type: Direct	Company Rep	ort Number			
Outcome	PT	Dancast C		ore remittee;		Age: 18 YR	Gender: Male
Other	Arthralgia	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
	Cheilitis	Health Professional	Accutane	PS .	Roche	ORAL	113
	Depression Nec		Bicillin C-R	C			
	Vision Abnormal Nec		Amoxicillin	C			
			Pce	c			
Date: 05/23/1991	ISR Number: 751005-3	Report Type: Direct	Сопрану Кер	ort Number:		Age: 39 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Alcohol Intolerance Apathy	Health Professional	Accutane	PS	Roche	ORAL	
	Condition Aggravated		Prozac	С		ORAL	32
	Depression Nec						
Date: 06/11/1991	ISR Number: 751891-7	Report Type: Direct	C P				
Outcome	TOWN	-	Company Rep	ort Number:		Age: 22 YR	Gender: Female
Other	PT Alopecia	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Ошег	Constipation	Consumer	Accutane	PS	Roche	ORAL	55
	Depression Nec		Triavil 2-10	С			33
	Photosensitivity Reaction Nos						
Date: 06/07/1991	ISR Number: 753224-9	Report Type: Periodic	Company Rep	ort Number: 900201	166001	Age: 15 YR	Gender: Male
Outcome	PT	Report Source	Product			13 IK	Gender: Male
Other	Depression Nec	Health Professional		Role	Manufacturer	Route	Dose/Unit Duration
	Leucopenia Nos		Accutane	PS	Roche	ORAL	94
D 4 05 07 110 -			Anafranil	C			
Date: 06/07/1991	ISR Number: 753251-1	Report Type: Periodic	Company Rep	rt Number: 910200	474001	Age: 16 YR	Gender: Male
Outcome	PT	Report Source	Product				Gender: Male
Hospitalization -	Hostility	Health Professional	·	Role	Manufacturer	Route	Dose/Unit Duration
Initial or Prolonged	Personality Disorder Nos		Accutane	PS	Roche	ORAL	26
Date: 06/07/1991	ISR Number: 753258-4	Report Type: Periodic	Company Repo	rt Number: 9002011	399001	Age: 31 YR	Gender: Female
Outcome	PT	Report Source	Product	h.ı	16	-	
Other	Alopecia	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit Duration
			· evverage	PS	Roche	ORAL,	62

Date: 04/16/1991	ISR Number: 743620-8	Report Type: Direct	Company Rep	ort Number:	-	Age: 18 YR	Gender: Male
Outcome	PT	Report Source	Product				
Death	Depression Nec	Health Professional	Accutane	Role PS	Manufacturer Roche	Route	Dose/Unit Duration 98
Date: 04/02/1991	ISR Number: 745098-7	Report Type: Direct	Company Rep	ort Number			
Outcome	PT	Dancast C		ore remittee;		Age: 18 YR	Gender: Male
Other	Arthralgia	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
	Cheilitis	Health Professional	Accutane	PS .	Roche	ORAL	113
	Depression Nec		Bicillin C-R	C			
	Vision Abnormal Nec		Amoxicillin	C			
			Pce	c			
Date: 05/23/1991	ISR Number: 751005-3	Report Type: Direct	Сопрану Кер	ort Number:		Age: 39 YR	Gender: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Other	Alcohol Intolerance Apathy	Health Professional	Accutane	PS	Roche	ORAL	
	Condition Aggravated		Prozac	С		ORAL	32
	Depression Nec						
Date: 06/11/1991	ISR Number: 751891-7	Report Type: Direct	C P				
Outcome	TOWN	-	Company Rep	ort Number:		Age: 22 YR	Gender: Female
Other	PT Alopecia	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
Ошег	Constipation	Consumer	Accutane	PS	Roche	ORAL	55
	Depression Nec		Triavil 2-10	С			33
	Photosensitivity Reaction Nos						
Date: 06/07/1991	ISR Number: 753224-9	Report Type: Periodic	Company Rep	ort Number: 900201	166001	Age: 15 YR	Gender: Male
Outcome	PT	Report Source	Product			13 IK	Gender: Male
Other	Depression Nec	Health Professional		Role	Manufacturer	Route	Dose/Unit Duration
	Leucopenia Nos		Accutane	PS	Roche	ORAL	94
D 4 05 07 110 -			Anafranil	C			
Date: 06/07/1991	ISR Number: 753251-1	Report Type: Periodic	Company Rep	rt Number: 910200	474001	Age: 16 YR	Gender: Male
Outcome	PT	Report Source	Product				Gender: Male
Hospitalization -	Hostility	Health Professional	·	Role	Manufacturer	Route	Dose/Unit Duration
Initial or Prolonged	Personality Disorder Nos		Accutane	PS	Roche	ORAL	26
Date: 06/07/1991	ISR Number: 753258-4	Report Type: Periodic	Company Repo	rt Number: 9002011	399001	Age: 31 YR	Gender: Female
Outcome	PT	Report Source	Product	h.ı	16	-	
Other	Alopecia	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit Duration
			· evverage	PS	Roche	ORAL,	62

Date: 06/07/1991	ISR Number: 753975-6	Report Type: Periodic		Company Report Numbe	r; 902013	93001	Age: 30 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Dala.	Manueline	•		
Other	Abdominal Pain Nos Emotional Disturbance Nos Malaise	Health Professional	Accutane Alcohol		PS C	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 62
Date: 06/07/1991	ISR Number: 753976-8	Report Type: Periodic		Company Report Numbe	r: 900201	391001	Age: 23 YR	Gen	der: Female
Outcome	PT	Report Source	Product	_	Role	Manufacturer	Route	Dose/Unit	D
Other	Amblyopia Nos Anxiety Nec Myasthenic Syndrome	Health Professional	Accutane Prednisone		PS C	Roche	ORAL	Dustromit	Duration 65
Date: 06/07/1991	Paraesthesia Nec ISR Number: 753983-5	Report Type: Periodic		Company Report Numbe	r: 900201	369001	Age: 17 YR		
Outcome	<u>PT</u>	Report Source	Product				-	Gen	der: Male
Other	Abnormal Dreams Asthenia	Health Professional	Accutane	· · · · · · · · · · · · · · · · · · ·	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 154
	Depression Nec Headache Nos								
Date: 06/07/1991	ISR Number: 753994-X	Report Type: Periodic		Company Report Number	r: 900201	348001	Age: 38 YR	Gen	der: Female
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	Route	D	•
Other	Alopecia Depression Nec	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration 153
	Dry Skin Skin Atrophy		Minocin		С		Okras		155
Date: 06/07/1991	ISR Number: 754077-5	Report Type: Periodic		Company Report Number	900201	302001	Age: 18 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route		
Other	Depression Nec Emotional Disturbance Nos Hyperlipidaemia Nos	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit_	Duration 14
Date: 06/07/1991	ISR Number: 754090-8	Report Type: Periodic		Company Report Number	900201	258001	Age: 17 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacture	•		
Other	Depression Nec	Health Professional	Accutane		Kole	Manufacturer	Route	Dose/Unit	Duration

		į	nananan	e Event Reports Of Information	((0))	Report			
Date: 06/07/1991	ISR Number: 754176-8	Report Type: Periodic		Company Report Number	r: 910200;	271001	Age: 22 YR	Gend	ler: Unknown
Outcome	PT	Report Source	Product				-		
Other	Alopecia	Consumer	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
	Arthritis Nos Depression Nec				rs	Roche	ORAL		
	Vision Abnormal Nec								
Date: 06/07/1991	ISR Number: 754177-X	Report Type: Periodic		Company Report Numbe	r: 910200	270001	Age:		
Outcome	PT	Report Source	D	. , .			Age:	Gend	ler: Unknown
Other	Amblyopia Nos	Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Back Pain	Communica	Accutane		PS	Roche	ORAL		1
	Cheilitis								
D-4 06/07/1004	Depression Nec								
Date: 06/07/1991	ISR Number: 754182-3	Report Type: Periodic		Company Report Numbe	r: 9102002	277001	Age: 43 YR	Gend	ler: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	D	
Other	Abdominal Pain Nos Depression Nec	Consumer	Accutane		PS	Roche	ORAL	Dose/Unit	Duration
	Headache Nos					1 COULD	OKAL		14
	Vision Abnormal Nec								
Date: 06/07/1991	ISR Number: 754183-5	Report Type: Periodic	* *	Company Report Numbe	r: 9102002	74001	Age:	Gend	ler: Unknown
Outcome	PT	Report Source	Product		Role	Manufacturer			
Other	Cyst Nos	Consumer	Accutane		PS	Roche	Route	Dose/Unit	Duration
	Depression Nec Infection Nos					Roche	ORAL		1826
	Vision Abnormal Nec								
Date: 06/07/1991	ISR Number: 754194-X	D475 - D							
Outcome		Report Type: Expedited (13-Day)	Company Report Number	r: 9102003	00001	Age: 20 YR	Gend	ler: Male
Hospitalization -	PT Amnesia Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Haematuria Present	Consumer	Accutane		PS	Roche	ORAL		27
	Hostility								=-
	Laboratory Test Abnormal Nos								
Pate: 06/07/1991	ISR Number: 754268-3	Report Type: Periodic		Company Report Number	r: 9002014	48001	Age: 28 YR	Gend	ler: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route		
Other	Dry Eye Nec	Health Professional	Accutane		PS	Roche		Dose/Unit	Duration
	Dry Skin Dyspareunia Nec				-~	a south	ORAL		141
	Vaginitis								

Date: 06/07/1991					A				
	ISR Number: 754272-5	Report Type: Periodic		Company Report Numb	er: 910200	021001	Age:	Ger	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route		
Other	Alopecia	Health Professional	Accutane		PS	Roche		Dose/Unit	Duration
	Conjunctivitis Nec Face Oedema					Rocae	ORAL		
	Hallucination Nos								
Date: 06/07/1991	ISR Number: 754289-0	Report Type: Periodic		Company Report Numb	er: 910200	074001	Age: 31 YR	Ger	der: Female
Outcome	PT	Report Source	Product						mer. remaie
Other	Dry Skin	Health Professional	Accutane	 	Role	Manufacturer	Route	Dose/Unit	Duration
	Electrocardiogram Abnormal		Retin-A		PS	Roche	ORAL		148
	Nos Palpitations				С				
	Supraventricular Extrasystoles		Cleocin		С				
Date: 06/07/1991	ISR Number: 754292-0								
	15K (VUINDET: 754292-0	Report Type: Periodic		Company Report Numb	er: 910200	086001	Age: 16 YR	Ger	der: Male
Outcome	PT	Report Source	Product		Role				
Other	Dry Skin	Health Professional	Accutane			Manufacturer	Route	Dose/Unit_	Duration
	Emotional Disturbance Nos		riccamic		PS	Roche	ORAL		18
	Hostility			_					
Date: 06/07/1991	ISR Number: 754393-7	Report Type: Periodic		Company Report Numb	am 900201	045001			
Outcome	PT	D	_	Pairy stepote 14millo	E1. 300201	343001	Age: 25 YR	Gen	der: Female
Other	Abnormal Dreams	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Chest Pain	Health Professional	Accutane		PS	Roche	ORAL		48
	Nausea		Triphasil		C				••
			Tetracycline	4	C		- +		
Date: 06/07/1991	ISR Number: 754700-5	Report Type: Periodic		Company Report Numb	010000				
Outcome	PT	•		Company Report Numb	er: 910200	151001	Age: 45 YR	Gen	der: Male
Other	Arthralgia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Out	Condition Aggravated	Health Professional	Accutane		PS	Roche	ORAL		32
	Depression Nec								32
Date: 06/07/1991	ISR Number: 754713-3					 			
	4556 140HIDEE: /34/13-3	Report Type: Periodic		Company Report Number	er: 910200	186001	Age: 30 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacture			
Other	Amblyopia Nos	Health Professional	Accutane			Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Cleocin		PS	Roche	ORAL		31
	Diarrhoea Nos Epistaxis		Ciexin		C				

		1	reston	e Evant Repair. Of Information		Regort			
Date: 06/07/1991	ISR Number: 754716-9	Report Type: Periodic							
Outcome	PT	• ••		Company Report Numb	er: 910200	191001	Age: 38 YR	Gen	der: Female
Other	Dysphonia	Report Source	Product	 	Role	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Accutane		PS	Roche	ORAL		150
Date: 06/07/1991	ISR Number: 754723-6	Report Type: Periodic		Company Report Numb	er: 910200	207001	Age:		
Outcome	PT	Report Source	Product				_	Gen.	der: Male
Disability	Drug Ineffective	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos				PS	Roche	ORAL		22
	Headache Nos Weight Increased		Tetracycline	:	С				
Date: 06/07/1991	ISR Number: 754783-2								
Outcome		Report Type: Periodic		Company Report Numb	er: 910200	322001	Age: 21 YR	Gen	der: Female
Other	PT Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Outer	Emotional Disturbance Nos	Health Professional	Accutane		PS	Roche	ORAL	2000 Unit	121
Date: 06/07/1991	ISR Number: 754784-4	Report Type: Periodic	· · · · · · · ·	Company Report Numb	er: 910200	343001	Age: 27 YR	Gene	
Outcome	PT	Report Source	Product		D.1	3e .	_		Tomac
Hospitalization - Initial or Prolonged	Depression Nec	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
Other	Dizziness (Exc Vertigo)				rs	Roche	ORAL		162
Date: 06/07/1991	ISR Number: 754801-1	Report Type: Periodic							
Outcome	PT			Company Report Number	er: 9102002	215001	Age: 24 YR	Gene	der: Male
Other	Dyspnoea Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Palpitations	Health Professional	Accutane		PS	Roche	ORAL		53
- i	Supraventricular Extrasystoles								
Date: 06/07/1991	ISR Number: 754816-3	Report Type: Periodic		Company Report Number	0102000	229001			
Outcome	PT	Report Source		pany acopore ranges	1. 3102002	236001	Age: 34 YR	Gene	der: Female
Other	Alopecia	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Treatm 1 foressions	Accutane		PS	Roche	ORAL		84
Date: 06/07/1991	ISR Number: 754820-5	Report Type: Periodic		Company Report Numbe	r: 9102002	250001	A 16377		 -
Outcome	PT	Report Source	Product		_	· ·	Age: 16 YR	Gend	der: Female
Other	Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Rectal Bleeding		Accutane		PS	Roche	ORAL		124
08/03/2000									
							F	age 62	of 487

Date 06.071/1991 SR Number: 754916-6 Report Type: Periodic Company Report Number: 900200573001 Age: 46 YR Doer/Unit Duration Product Role Rocks Rocks ORAL Oration Or
Outcome FT Report Source Product Role Manufacturer Route Down/tule Down/tule Product Role Manufacturer Route Open/tule Down/tule
Column Aspecia Aspe
Part
Onle (c) 00/07/1910 SR Number: 754952-1 Report Type: Periodic outcome Company Report Number: 90020014101 Age: 19 YR Gender: 10 00001/10 00000000000000000000000000
Delicone PT
Product Pro
Health Professional Health Professional Health Professional Health Professional Health Professional Health Professional From the professional From the professional Health Professi
Outcome PT Report Source Product Role Manufacturer Rout Dose/Unit Duration Other Chelitiis Health Professional Accutane PS Roche ORAL 15 T 15 T Dutcome PT Report Type: Periodic Company Report Number: 91020032c001 Age: 15 YR Gender: Product Product Roche ORAL 15 T Product Product Roche Natural Section Product Report Type: Periodic Company Report Number: 91020032c001 Age: 15 YR Gender: Product Product Roche ORAL 15 T 15 T 15 T Nate: 06/07/1991 ISR Number: 755524-5 Report Type: Periodic Company Report Number: 910200358001 Age: 17 YR Gender: Male Male Dutcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Dutcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration Chest Pain Product Roche
Product Product Role Manufacturer Rout Dose/Unit Duration Dutcome Product Role Manufacturer Rout Dose/Unit Duration Dutcome Product Role
Emotional Disturbance Nos Epistaxis Accutane PS Roche ORAL 15 \ Total Interview In
Outcome PT Report Source Product Role Manufacturer Route Dose/Unit Duration School PT Report Source Product Role Manufacturer Route Dose/Unit Duration Ist Number: 755524-5 Report Type: Periodic Company Report Number: 910200358001 Age: 17 YR Gender Male Other Arrhythmia Nos Chest Pain Chest Pain Palpitations Ist Number: 755533-6 Report Type: Periodic Company Report Number: 910200358001 Age: 17 YR Gender Male Other Arrhythmia Nos Chest Pain Palpitations Ist Number: 755533-6 Report Type: Periodic Company Report Number: 910200352001 Age: 17 YR Gender Male Other Manufacturer Route Dose/Unit Duration Ist Number: 755533-6 Report Type: Periodic Company Report Number: 910200352001 Age: 17 YR Gender Male Other Other Report Source Product Route PS Roche ORAL Duration Other Other Report Source Product Route PS Roche ORAL 148 Other Duration PT Report Source Product Route PS Roche ORAL 148 Other Duration PS Roche ORAL 148 Other Dury Indiffective Dry Skin Emotional Disturbance Nos
PT
Emotional Disturbance Nos Health Professional Accutane PS Roche NorAL 15 15 15 15 15 15 15 1
Accutane Company Report Number: 910200358001 Age: 17 YR Gender: Male
Dutcome PT Report Source Product Rober 910200358001 Age: 17 YR Gender: Male Dutcome PT Report Source Product Rober PS Roche ORAL 15 Dutcome PT Report Source Product Rober PS Roche ORAL 15 Tale: 06/07/1991 ISR Number: 755533-6 Report Type: Periodic Company Report Number: 910200392001 Age: 17 YR Gender: Male Dutcome PT Report Source Product Rober Roche ORAL 148 Dutcome PT Report Source Product Rober Manufacturer Route Dose/Unit Duration Dutg Ineffective Dry Skin Emotional Disturbance Nos
Arrhythmia Nos Chest Pain Acottane Product Role Manufacturer Route ORAL 15 15 15 15 15 15 15 15
Chest Pain Pulpitations Accutane PS Roche ORAL 15
Age: 17 YR Gender: Male Outcome PT Report Source Product Role Manufacturer Route DuscoVinit Duration Other Cheilius Health Professional Accutane PS Roche ORAL 148 Dry Skin Emotional Disturbance Nos
Dutcome PT Report Source Product Role Manufacturer Route Dusce/Unit Duration Cheilitis Health Professional Accutane PS Roche ORAL 148 Dry Skin Emotional Disturbance Nos
Dither Cheilitis Health Professional Accutane PS Roche ORAL 148 Dry Skin Emotional Disturbance Nos
Drug Ineffective Health Professional Accutane PS Roche ORAL 148 Dry Skin Emotional Disturbance Nos
Dry Skin Emotional Disturbance Nos
ate: 06/07/1991 ISR Number: 755549-X Report Type: Periodic Company Report Number: 900200522001 Age: 24 YR Gender: Female
Julicome PT Report Source Product Pl. Manufactus
Aguation Health Professional Acoutane PS Rocks
Depression Nec PS Roche ORAL 169 Dry Mouth
08/03/2000
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Pater DENTITION		PA.	- Advers Restora	Event Reports Af Info ens cion		ten (AERS) Report				
Date: 06/07/1991	ISR Number: 755586-5	Report Type: Periodic		Company Report Number	: 910200	461001	Age: 34 YR			
Outcome	PT	Report Source	Product	•				Gen	der: Male	
Other	Impotence	Health Professional	Accutane		PS	Manufacturer Roche	Route	Dose/Unit	Duration	
Date: 06/07/1991	ISR Number: 755596-8	December 19 1 11					ORAL		167	
Outcome	PT	Report Type: Periodic		Company Report Number	900200	537001	Age:	Gen	der: Female	-
Other	Condition Aggravated	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D	
: !	Confusion	Study	Accutane		PS	Roche	ORAL	DOSE/CHIL	Duration	
	Oedema Nos	Health Professional					OICAL			
	Renal Failure Nos									
Date: 06/07/1991	ISR Number: 755631-7	Report Type: Periodic		Company Report Number	. 0000000	140001				
Outcome	PT .	Report Source		Company Report Number	9002007	48001	Age: 28 YR	Gen	der: Female	
Other	Depression Nec	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Migraine Nos	I vicosionar	Accutane		PS	Roche	ORAL		40	
	Urine Abnormal Nos Vision Abnormal Nec									
Date: 06/07/1991	ISR Number: 755633-0									
Outcome		Report Type: Periodic		Company Report Number	9002007	53001	Age: 34 YR	Gen	der: Male	
Other	PT Dry Skin	Report Source	Product		Role	16			wei. Maie	
Julia	Hypertension Nos	Consumer	Accutane		PS	Manufacturer Roche	Route	Dose/Unit	Duration	
	Muscle Twitching					Roche	ORAL		60	
	Palpitations									
Date: 06/07/1991	ISR Number: 755639-1	Report Type: Periodic					 		~	
Outcome	PT			Company Report Number:	9002014	16001	Age: 31 YR	Gene	der: Female	
Other	Arrhythmia Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Electrocardiogram Abnormal	Health Professional	Accutane		PS	Roche	ORAL	- Jac Citt	48	
	Nos Palpitations		Hydroxyzine		C				48	
ate: 06/07/1991	ISR Number: 755698-6									
utcome		Report Type: Periodic		Company Report Number:	9002013	97001	Age: 15 YR	Gand	ler: Female	
ospitalization -	PT Anhralgia	Report Source	Product		Role	Manufacturer	_			
itial or Prolonged	Depression Nec	Study	Accutane		PS PS	Roche		Dose/Unit	Duration	
	Headache Nos	Health Professional		•	-	TOTALIC .	ORAL		86	
	Personality Disorder Nos									

				e Evert Reporti		TOTAL ALLERS			
				Offictormation		REPORT			
Date: 06/07/1991	ISR Number: 755844-4	Report Type: Periodic			***********				
		Report Type: Periodic		Company Report Number	r: 900200	474001	Age: 15 YR	Gen	ider: Male
Outcome	PT Abdominal Pain Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec	Health Professional	Accutane		PS	Roche	ORAL		117
	Emotional Disturbance Nos						·. 4—		117
· · · · · · · · · · · · · · · · · · ·	Headache Nos								
Date: 06/07/1991	ISR Number: 755846-8	Report Type: Periodic		Company Report Numbe	- 000200	470001			
Outcome	PT	Damant C		Tany Report Hambe	1. 700200	470001	Age: 30 YR	Gen	nder: Female
Other	Depression Nec	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Dry Skin	racam rosessional	Accutane		PS	Roche	ORAL		
	Dyspareunia Nec		Thorazine		C				
	Vaginitis								
Date: 06/07/1991	ISR Number: 755847-X	Report Type: Periodic		Company Report Numbe	r: 900200	460001	Age: 37 YR	Gen	ider: Female
Outcome	Pr	Report Source	Product		D-1-				
Other	Libido Decreased	Health Professional	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
Date: 06/07/1991						Rodie	ORAL		42
Date: 00/07/1991	ISR Number: 756223-6	Report Type: Periodic		Company Report Numbe	r: 900200	420001	Age: 33 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route		
Other	Asthenia Cellulitis	Health Professional	Accutane		PS	Roche		Dose/Unit	Duration
	Depression Nec					recall:	ORAL		42
	Dermatitis Nos								
Date: 07/07/1991	ISR Number: 762362-6	Report Type: Periodic	· · · · · · · · · · · · · · · · · · ·	C					
Outcome	PT			Company Report Numbe	r: 890200:	320001	Age: 25 YR	Gen	der: Male
Other	Emotional Disturbance Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Hypercholesterolaemia	Health Professional	Accutane		PS	Roche	ORAL		178
	Hyperlipidaemia Nos			:					
	Influenza Like Illness								•
Date: 09/09/1991	ISR Number: 771120-8	Report Type: Expedited (15-Day)	Company Report Number	r: 9102011	131001	Age:		der: Female
Outcome	PT	Report Source	Product						der: Female
Hospitalization -	Dyspareunia Nec	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Urinary Tract Infection Nos Vaginitis				гъ	Roche	ORAL		

Date: 09/04/1991	ISR Number: 771125-7	Report Type: Expedited	(15-Day)	Company Report Num	iber: 910201	137001	Age: 14 YR	Gend	er: Male
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Catatonia Hallucination Nos Paranoia Psychotic Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL		2
Date: 09/12/1991	ISR Number: 775500-6	Report Type: Direct		Company Report Nun	iber:		Age: 40 YR		er: Female
Outcome	PT	Report Source	Product				=	Gain	er: remaie
Other	Arthritis Nos	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Influenza Like Illness		Vitamin A		PS SS	Roche			
D + 00004004	Photosensitivity Reaction Nos								
Date: 09/20/1991	ISR Number: 776989-9	Report Type: Direct		Company Report Num	ber:		Age:	Gend	er: Male
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D
	Amblyopia Nos Back Pain Depression Nec	Consumer	Accutane		PS	Roche	ORAL	DoseyUnit	Duration 90
	Dry Mouth								
Date: 09/20/1991	ISR Number: 777487-9	Report Type: Direct	·	Company Report Nun	ber:		Age: 14 YR	Gend	er: Unknown ·
Outcome	PT	Report Source	Product		Role	Manufacturer	D4-		
	Arthritis Nos	Consumer	Accutane		PS	Roche	Route	Dose/Unit	Duration
	Depression Nec Photosensitivity Reaction Nos Vision Abnormal Nec				15	Rode	ORAL		147
Date: 09/20/1991	ISR Number: 778954-4	Report Type: Direct	-	Company Report Nun	hen.				
Outcome	PT			company resport rum	DCI.		Age:	Gend	er: Male
	Back Pain	Report Source Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Influenza Like Illness	Consumer	Accutane		PS	Roche			
Date: 10/03/1991	ISR Number: 780023-4	Report Type: Direct		Company Report Num	ber:		Age:	Gende	er: Unknown
Outcome	PT	Report Source	Product		Role	Manufacturer	D4-	D 77.11	
	Cyst Nos	Consumer	Accutane		PS	Roche	Route	Dose/Unit	Duration
	Depression Nec Influenza Like Illness					ACAHE			1826
	THE POST LAKE THESE								

Date: 10/18/1991	ISR Number: 785566-5	Report Type: Expedited ([5-Day)	Company Report Number	r: 910700	271001	Age:		
Outcome Death	PT Major Depressive Disorder Nos Suicide Attempt	Literature	Product Roaccutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Unknown Duration 120
Date: 10/30/1991	ISR Number: 789216-3	Health Professional Report Type: Direct		Company Report Number			Age: 42 YR		
Outcome Hospitalization - Initial or Prolonged	PT Anthritis Nos Depression Nec	Report Source Consumer	Product Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 93
Disability	Infection Nos Vision Abnormal Nec						•		
Outcome	ISR Number: 815546-2 PT	Report Type: Expedited (1 Report Source		Company Report Number	9108002	213001	Age: 17 YR	Gen	ader: Male
Hospitalization - Initial or Prolonged	Depression Nec Headache Nos Insomnia Nec Mania	Foreign Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 14
Date: 04/15/1992	ISR Number: 833866-2	Report Type: Direct		Company Report Number	:		Age: 31 YR	Gen	der: Male
Outcome	PT Dry Skin Personality Disorder Nos	Report Source Health Professional	Product Accutane	·	Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
	Speech Disorder Nec Tooth Disorder Nos								
Date: 05/13/1992 Outcome	ISR Number: 840102-X	Report Type: Expedited (15	5-Day)	Company Report Number	9201002	01001	Age: 32 YR	Gen	der: Male
	Asthenia Depression Nec Dyspnoca Nos Myalgia	Report Source Poreign Health Professional	Product Roaccutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration
Date: 06/18/1992	ISR Number: 848612-6	Report Type: Periodic		Company Report Number:	9102008	78001	Age: 36 YR	Gen	der: Female
Outcome Other	PT Depression Nec Emotional Disturbance Nos	Report Source Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration 40
	Headache Nos Myalgia								errore,

			2/4/1111	af Information	(1)	Report			
Date: 06/18/1992	ISR Number: 848804-6	Report Type: Periodic		Company Report Number	r: 920200	358001	Age:	Gen	ider: Female
Outcome	PT	Report Source	Product		D-1-		•		-
Other	Depersonalisation	Health Professional	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
Date: 06/18/1992	ISR Number: 848813-7		· · · · · · · · · · · · · · · · · · ·			Rodie	ORAL		
		Report Type: Periodic		Company Report Number	r: 920200	388001	Age: 25 YR	Gen	ider: Male
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	D4-	5 ** • •	
Other	Dyspepsia Headache Nos	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
	Impotence				20	NOTIC	ORAL		33
Date: 06/18/1992	ISR Number: 848818-6	Depart Trans. D							
Outcome		Report Type: Periodic		Company Report Number	r: 920200	386001	Age: 19 YR	Gen	ider: Male
Other	Pr	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D
Outer.	Personality Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL	Dose Unit	Duration
Date: 06/18/1992	ISR Number: 849190-8	Report Type: Periodic		Company Report Numbe	r: 920200:	519001	Age: 14 YR		der: Female
Outcome	PT	Report Source	Product				-		remaie
Other	Convulsions Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Diarrhoea Nos Hallucination Nos		Erythromycir	,	PS	Roche	ORAL		1
<u> </u>	Headache Nos		_ yanoniyin	•	С				
Date: 06/18/1992	ISR Number: 849191-X	Denove The D							
Omtoo		Report Type: Periodic		Company Report Numbe	r: 9202005	522001	Age: 19 YR	Gen	der: Female
Outcome Other	PT Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Domestical
Julia	Insomnia Nec	Health Professional	Accutane		PS	Roche	ORAL	DOSO CHIL	Duration
	Thinking Abnormal Nec				-		UKAL		117
ate: 06/18/1992	ISR Number: 849193-3	Report Type: Periodic							
Outcome				Company Report Number	r: 9202005	27001	Age: 39 YR	Gen	der: Female
Other	PT Condition Aggravated	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Health Professional	Accutane		PS	Roche	ORAL	Olit	61
	Emotional Disturbance Nos		Klonopin		C				OI.
	 		Trifluoperazir	ne .	c				
nte: 06/18/1992	ISR Number: 849196-9	Report Type: Periodic		Company Report Number	9202004	61001	Age: 20 YR		3
Outcome	PT	Report Source	Product				•	Gen	der: Male
Other	Anxiety Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		vremane		PS	Roche	ORAL		149

		1	reedom	i Event Reporti Of Information		Report				
Date: 06/18/1992	ISR Number: 849212-4	Report Type: Periodic		Company Report Numbe	n: 920200	463001	Age: 23 YR	Ge	nder: Female	
Outcome	PT	Report Source	Product		Role	Manufacturer	.			
Other	Cough	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration	
	Dysphonia Infection Nos				13	Roche	ORAL		63	
	Pharyngitis Nos									
Date: 06/18/1992	ISR Number: 849227-6	Report Type: Periodic		Company Report Numbe	- 020200					
Outcome	PT	D4 @		Company Report Number	r: 920200	034001	Age: 24 YR	Ger	ıder: Male	
Other	Depression Nec	Report Source Health Professional	Product	· · · · · · · · · · · · · · · · · · ·	Role	Manufacturer	Route	Dose/Unit	Duration	
		ricann Professional	Accutane		PS	Roche	ORAL			
Date: 06/18/1992	ISR Number: 850217-8	Report Type: Periodic		Company Report Numbe	r: 910201	470001	Age: 20 YR		ıder: Male	_
Outcome	PT	Report Source	Product					Gu	ider: Male	
Other	Arthralgia	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
	Cheilitis Insomnia Nec		Ampicillin		PS C	Roche	ORAL		99	
ate: 06/18/1992					<u>. </u>					
, -	ISR Number: 850237-3	Report Type: Periodic		Company Report Number	r: 920200	510001	Age: 23 YR	Ger	ıder: Male	
Outcome	PT	Report Source	Product					- Ga	ider: Male	
Other	Blepharitis	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
	Depression Nec Emotional Disturbance Nos				PS	Roche	ORAL		26	
	Paranoia									
ate: 06/18/1992	ISR Number: 850239-7	Report Type: Periodic								
Outcome	D.T.	steport type, remonic		Company Report Number	920200	506001	Age: 19 YR	Gen	der: Female	
Other	PT Palpitations	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D41	
	1 aspitations	Health Professional	Accutane		PS	Roche	ORAL	Dose Citt	Duration	
			Erythromycir	1	С		OKAL		29	
ate: 06/18/1992	ISR Number: 850240-3	Report Type: Periodic		Company Report Number	000000					_
outcome	PT	Demont C		Company Report Number	; 9202000	02001	Age: 22 YR	Gen	der: Female	
Other	Confusion	Report Source Health Professional	Product	·	Role	Manufacturer	Route	Dose/Unit	Duration	
	Depersonalisation	ricam ricaessional	Accutane		PS	Roche	ORAL			
	Depression Nec	·	-							
ite: 06/18/1992	ISR Number: 850249-X	Report Type: Periodic		Company Report Number	. 0202000	42001				
utcome	PT	Dannet Communication			. 7202003	43001	Age: 31 YR	Gen	der: Male	
ther	Arthritis Nos	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Depression Nec	ricaun Professional	Accutane		PS	Roche	ORAL		100	

			rectors	Eventikeport Of hiloroxides		Report	200		
Date: 06/18/1992	ISR Number: 850283-X	Report Type: Periodic		Company Report Numb	er: 910201	601001	Age: 28 YR	Gen	der: Male
Outcome	PT	Report Source	Product					·	act. Wate
Other	Impotence	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
Date: 06/18/1992	·				P3	Roche	ORAL		15
Date: 00/18/1992	ISR Number: 850662-0	Report Type: Periodic		Company Report Numb	er: 910201	720001	Age: 38 YR	Gend	ier: Pemale
Outcome	PT	Report Source	Product					Gain	et. remaie
Other	Cheilitis	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
	Corneal Lesion Nos Emotional Disturbance Nos			•	rs	Roche	ORAL		38
	Epistaxis								
Date: 06/18/1992	ISR Number: 850664-4								
-		Report Type: Periodic		Company Report Number	er: 910201	718001	Age: 18 YR	Gend	ier: Female
Outcome Other	PT	Report Source	Product		Role	Manufacturer	Route	D. 67. u	
Other	Emotional Disturbance Nos	Health Professional	Accutane		PS	Roche		Dose/Unit	Duration
Date: 06/18/1992	ISR Number: 850689-9					KKAIE	ORAL		13
_	19K Number: 630089-9	Report Type: Periodic		Company Report Number	er: 910201	757001	Age: 38 YR	Gend	ier: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	- .		
Other	Glaucoma Nos Headache Nos	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
	Thinking Abnormal Nec					ROLLE	ORAL.		128
Pate: 06/18/1992	ISR Number: 850696-6								•
_		Report Type: Periodic		Company Report Number	er: 910201	544001	Age: 24 YR	Gend	ler: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	P		
Other	Confusion Hallucination Nos	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
•	Headache Nos			-		Kocale	ORAL		1
Pate: 06/18/1992	ISR Number: 850697-8								
	101C 144HDEL: 030097-0	Report Type: Periodic		Company Report Number	r: 910201	541001	Age: 23 YR	Gend	ler: Male
Outcome	PT	Report Source	Product		Role	Manufastur	-		
Other	Impotence	Health Professional	Accutane		PS	Manufacturer Roche	Route	Dose/Unit	Duration
ate: 06/18/1992	ISR Number: 850903-X					NAME	ORAL		9
_		Report Type: Periodic		Company Report Number	r: 910201:	577001	Age: 27 YR	Gend	ler: Male
outcome	PT	Report Source	Product		Role	Manufacturer	Route	Description	
ther	Depression Nec Dermatitis Nos	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration
	Dizziness (Exc Vertigo)						UKAL		3
	Tachycardia Nos								

		1111	101101	e Event Repor	ing si	Stem (AERS)			
			e estion	Of hitomatic		i Report			
Date: 06/24/1992	ISR Number: 851232-0	Report Type: Expedited	(15-Day)	Company Report Nun	nher: 920200	1962001	Age: 40 YR		
Outcome	PT	Report Source	Product				ge. 40 I N	. Gai	der: Female
Hospitalization -	Major Depressive Disorder Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Suicide Attempt		Prozac		PS C	Roche	ORAL		86
Date: 06/18/1992	ISR Number: 851241-1	Report Type: Periodic		Company Report Num	her: 91020	1001001	Age: 16 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer			
Other	Anxiety Nec Tremor Nec	Health Professional	Accutane		PS	Roche	Route ORAL	Dose/Unit	Duration 151
Date: 06/18/1992	ISR Number: 851311-8	Report Type: Periodic				·	<u> </u>		
Outcome	PT			Company Report Num	ber: 910201	808001	Age: 30 YR	Gen	der: Male
Other	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
·	Emotional Disturbance Nos Nervousness	Health Professional	Accutane		PS	Roche	ORAL	<u> Dosc om</u>	106
Date: 06/18/1992									
Date: 00/18/1992	ISR Number: 851322-2	Report Type: Periodic		Company Report Num	ber: 910201	815001	Age: 25 YR	Gen	der: Male
Outcome	PT	Report Source	Product				0	Gai	uer; male
Other	Thinking Abnormal Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
			Eryc		PS	Roche	ORAL		43
Date: 06/18/1992	ISR Number: 851341-6		11170		С				
	ADIC (GHILDER: 0.31341-0	Report Type: Periodic		Company Report Num	ber: 910201	790001	Age: 26 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	N	- ·		
Other	Dry Mouth	Health Professional	Accutane		PS	Manufacturer	Route	Dose/Unit	Duration
D. (Dysphonia				13	Roche	ORAL		427
Date: 06/18/1992	ISR Number: 851345-3	Report Type: Expedited (15-Day)	Company Report Num	her: 910201	575001	A 4:		
Outcome	_ PT	Report Source	Devis	· , superior		2,5001	Age: 41 YR	Gen	der: Female
Disability	Amblyopia Nos	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Lipodystrophy	A LONG SECONDARY	Accutane		PS	Roche	ORAL		60
	Major Depressive Disorder Nos Thyroiditis Nos		Hismanal		С				
Date: 06/18/1992	ISR Number: 851487-2	Report Type: Periodic		Company Report Numl	er: 910201	723001	Age: 34 YR	Gene	der: Male
Outcome	PT	Report Source	Product					Juli	. Male
Other	Abdominal Pain Nos Impotence	Health Professional	Accutane		Role PS	Manufacturer Roche	ORAL.	Dose/Unit	Duration 2

Date: 06/18/1992 IS	SR Number: 851635-4	Report Type: Periodic		Company Report Num	ber: 920200	142001	Age: 26 YR		dan. 363	
Outcome	PT	Report Source	Product				-	Gen	der: Male	
Other	Alopecia	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration	
	Anxiety Nec Conjunctivitis Nec				rs	Roche	ORAL		82	
Date: 06/18/1992 IS	R Number: 851637-8	Report Type: Periodic		Company Report Num	ham 920200	110001				
Outcome	PT	Report Source	Product	1 V P		110001	Age: 17 YR	Gen	der: Male	
Other	Emotional Disturbance Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
	Headache Nos Hostility		Accutane		PS	Roche	ORAL		30	
Pate: 06/19/1992 IS	R Number: 851641-X	Report Type: Periodic		Company Report Num	her: 920200	131001	Age: 50 YR	Con	der: Female	
Outcome	PT	Report Source	Product		ъ.				uci. remate	
Other	Depression Nec	Health Professional	Accutane	·	PS	Manufacturer Roche	Route	Dose/Unit	Duration	
	Skin Atrophy Skin Hypertrophy		Estrace		C	Rocne	ORAL		93	
- <u> </u>			Premarin		c					
Date: 06/18/1992 IS	R Number: 851666-4	Report Type: Periodic		Company Report Numl		979001	Age: 34 YR			
Outcome	PT	Report Source	Product				Age. 34 IK	Gen	der: Male	
Other	Anxiety Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
Date: 06/18/1992 IS		 			PS	Roche	ORAL		76	
Date: 00/16/1992 IS	R Number: 851667-6	Report Type: Periodic		Company Report Numi	er: 910200	979002	Age:	Gm	der: Female	
Outcome	PT	Report Source	Product						uer: remaie	
Other	Depression Nec	Health Professional	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration	
Date: 06/18/1992 IS	R Number: 851696-2	Report Type: Periodic				-i.	ORAL			
Outcome	PT			Company Report Numb	er: 910201	552001	Age: 2 YR	Gen	der: Male	
	Blood Creatine Phosphokinase	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
:	Increased	Health Professional	Accutane		PS	Roche	ORAL	25 5 5 6 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	151	
	Insomnia Nec Nervousness								131	
Date: 06/18/1992 ISI	R Number: 851697-4	Report Type: Periodic		Company Report Numb						
Outcome	PT	· ·		hand vehat vamp	er: 9102016	21001	Age: 14 YR	Gen	der: Female	
Other	Depression Nec	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Emotional Disturbance Nos		Accutane		PS	Roche	ORAL		14	
	Headache Nos Hypedipidaemia Nos		Ortho-Novu	m 7/1/1	С					
08/03/2000		·								

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			account of	Of Information		Regue			
Date: 06/18/1992	ISR Number: 851698-6	Report Type: Periodic		Company Report Numb	er: 910201	1649001	Age: 34 YR		
Outcome	PT	Report Source	Product		-1020	.015001	Age: 34 1K	Ger	ider: Female
Other	Agitation	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration
	Sebormoea	Tanada i Torcasional	Accutane		PS	Roche	ORAL		
	Speech Disorder Nec Urticaria Nos								
Date: 06/18/1992	· · · · · · · · · · · · · · · · · · ·			*					
Date: 00/18/1992	ISR Number: 851751-7	Report Type: Periodic		Company Report Number	er: 920200	0573001	Age: 31 YR		nder: Female
Outcome	<u>PT</u>	Report Source	Product					Gen	ider: Female
Other	Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Migraine Nos		Accutation		PS	Roche	ORAL		30
Date: 06/18/1992	ISR Number: 851757-8	Report Type: Periodic		Company Report Number	010201	281001	· · · · · · · · · · · · · · · · · · ·	····	
Outcome	PT			hand wehat Million	ir: 910201	100196	Age: 37 YR	Gen	ider: Female
Other	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Accutane		PS	Roche	ORAL		
D 4 05404000			Lorazepam		C				
Date: 06/18/1992	ISR Number: 851758-X	Report Type: Periodic		Company Report Numbe	r: 910201	378001	Age: 42 YR	C	ıder: Female
Outcome	PT	Report Source	Product				11gc. 42 IK	Gen	ider: Female
Other	Amnesia Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Nervousness		Accutatie		PS	Roche	ORAL		56
Date: 06/18/1992	ISR Number: 851803-1	Report Type: Periodic		Company Report Numbe	010000	402004			
Outcome	PT	Dan 4 C		company Report Hunting	F: 910200	483001	Age: 18 YR	Gen	der: Male
Other	Personality Disorder Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Accutane		PS	Roche	ORAL		
Date: 06/18/1992	ISR Number: 851806-7	Report Type: Periodic		Company Barretti	040000		 		
Outcome	PT			Company Report Number	r: 910201:	258001	Age: 16 YR	Gen	der: Male
Other	Amblyopia Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Headache Nos	Health Professional	Accutane		PS	Roche	ORAL		25
	Hostility		Imipramine		С				
Date: 06/18/1992	ISR Number: 852025-0	Report Type: Periodic		Company Day 125					
Outcome	PT			Company Report Number	r: 910200:	89001	Age: 17 YR	Gen	der: Male
Hospitalization -	Major Depressive Disorder Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged		Health Professional	Accutane		PS	Roche	ORAL		32

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Date: 06/18/1992 Outcome	ISR Number: 852037-7	Report Type: Periodic		Company Report No	mber: 91020	0995001	Age: 18 YR	Gende	er: Male
Other	Hypoglycaemia Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Personality Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL		104
Date: 06/18/1992	ISR Number: 852043-2	Report Type: Periodic		Company Report Nu	mber: 91020	1805002	Age: 25 YR	Gende	
Outcome	PT	Report Source	Product					Gente	er: Female
Other	Alanine Aminotransferase Increased	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Aspartate Aminotransferase		Naprosyn		PS C	Roche	ORAL		397
	Increased Chest Pain		Proventil		c				
	Depression Nec				C				
Date: 06/18/1992	ISR Number: 852050-X	Report Type: Periodic		Company Report Nu	mber: 910200	0671001	Age: 38 YR	Gende	er: Female
Outcome	PT	Report Source	Product		Role	Manuel	- ·		- runne
Other	Amnesia Nec	Health Professional	Accutane		PS PS	Manufacturer	Route	Dose/Unit	Duration
	Syncope		Апаргох		C	Roche	ORAL		150
Outcome	ISR Number: 852280-7 PT	Report Type: Periodic	,	Company Report Nu	nber: 920200	086001	Age: 34 YR	Gende	r: Female
Other	Alopecia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit]	Duration
	Depression Nec	Health Professional	Accutane		PS	Roche	ORAL		92
Date: 07/07/1992	ISR Number: 852717-3	Report Type: Expedited (15-Day)	Company Report Nu	nber: 920201	008001	Age: 40 YR	Gende	
Outcome	PT	Report Source	Product					Gende	r: Female
Hospitalization -	Agitation	Health Professional	Accutane	 	Role	Manufacturer	Route	Dose/Unit 1	Duration
Initial or Prolonged Other	Depression Nec		recutatio		PS	Roche	ORAL	ŗ	95
	Dizziness (Exc Vertigo) Palpitations								
Date: 06/18/1992	ISR Number: 853032-4	Report Type: Periodic		Company Report Nur	sber: 910201	376001			
Outcome	_ PT	Report Source	D- 1 4	*			Age: 60 YR	Gende	r: Male
Other	Impotence	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit I	Duration
			Accutane		PS	Roche	ORAL		01
			Tenormin		С				
			Procardia		C.				
			Labetalol		С				

ISR Number: 853302-X PT Arthritis Nos Asthenia Depression Nec Tendon Disorder Nos ISR Number: 853365-1 PT Dysphonia Laryngitis Nos Pneumonia Nos Systemic Lupus Erythematosus ISR Number: 853374-2	Report Type: Periodic Report Source Consumer Report Type: Periodic Report Source Health Professional	Product Accutane Product Accutane	Company Report Nun Company Report Num	Role PS	Manufacturer Roche	Age: 19 YR Route ORAL Age: 19 YR	Gen Dose/Unit	der: Male <u>Duration</u> 1188 der: Female
Arthritis Nos Asthenia Depression Noc Tendon Disorder Nos ISR Number: 853365-1 PT Dysphonia Laryngitis Nos Pneumonia Nos Systemic Lupus Erythematosus	Consumer Report Type: Periodic Report Source	Accutane	Company Report Num	PS ber: 920200	Roche	ORAL		1188
Asthenia Depression Nec Tendon Disorder Nos ISR Number: 853365-1 PT Dysphonia Laryngitis Nos Pneumonia Nos Systemic Lupus Erythematosus	Report Type: Periodic	Product	Company Report Num	her: 920200	315001			1188
ISR Number: 853365-1 PT Dysphonia Laryngitis Nos Pneumonia Nos Systemic Lupus Erythematosus	Report Source		Company Report Num			Age: 19 YR	Gen	der: Female
PT Dysphonia Laryngitis Nos Pneumonia Nos Systemic Lupus Erythematosus	Report Source		Company Report Num			Age: 19 YR	Gen	der: Female
Dysphonia Laryngitis Nos Pneumonia Nos Systemic Lupus Erythematosus				Role		g 12 11C	Gen	uer: remaie
Laryngitis Nos Pneumonia Nos Systemic Lupus Erythematosus	Health Professional			Kole				
Pneumonia Nos Systemic Lupus Erythematosus		recutance			Manufacturer	Route	Dose/Unit	Duration
				PS	Roche	ORAL		156
ISR Number: 853374-2								
	Report Type: Periodic		Company Report Num	ber: 920200	060001	Age: 13 YR	Gen	der: Female
PT	Report Source	Product		D.1.	** * .	*		runae
Major Depressive Disorder Nos	Health Professional	Accutane		PS	Manufacturer Roche	Route	Dose/Unit	Duration 108
ISR Number: 853380-8	Report Type: Periodic		Company Report Num	per: 910200	981001	Age: 34 YR	Gen	
	Report Source	Product		D-1		_		Iviaic
	Health Professional	Accutane	-			Route	Dose/Unit	Duration
				PS	Roche	ORAL		55
	· · · · · · · · · · · · · · · · · · ·	<u> </u>						
	Report Type: Periodic		Company Report Numl	er: 910200	708001	Age: 15 YR	Gene	der: Male
	Report Source	Product		Dolo	35			Name
•	Health Professional	Accutane					Dose/Unit	Duration
	P- 47				Roche	ORAL		112
	Report Type: Periodic		Company Report Numb	er: 9102005	500001	Age: 23 YR	Gene	ier: Female
PT	Report Source	Product		D.1.	M	-		1 chare
Emotional Disturbance Nos	Health Professional	Accutane					Dose/Unit	Duration
SR Number: 853544-3	Percent Town Date "					ORAL		140
	suport Type: Periodic		Company Report Numb	er: 9102005	28001	Age: 41 YR	Gend	ler: Female
	Report Source	Product		Pole	Manufact			I CALLACE
•	Health Professional	Accutane					Dose/Unit	Duration
					Roche	ORAL		37
IS	Major Depressive Disorder Nos SR Number: 853380-8 PT Confusion Dizziness (Exc Vertigo) Dry Eye Nec Vision Abnormal Nec SR Number: 853392-4 PT Alopecia Depression Nec SR Number: 853529-7	Major Depressive Disorder Nos Report Source Health Professional Report Type: Periodic PT Report Source Health Professional Dizziness (Exc Vertigo) Dry Eye Nec Vision Abnormal Nec Report Type: Periodic Report Source Report Source Health Professional Report Source Health Professional Report Source Health Professional Report Type: Periodic PT Report Type: Periodic PT Report Source Health Professional Report Source Health Professional Report Type: Periodic PT Report Source Health Professional Report Type: Periodic Health Professional Report Type: Periodic Health Professional	Major Depressive Disorder Nos Health Professional Accutane SR Number: 853380-8 Report Type: Periodic PT Report Source Product Confusion Dizziness (Exc Vertigo) Dry Eye Nec Vision Abnormal Nec SR Number: 853392-4 Report Type: Periodic PT Report Source Product Alopecia Depression Nec Report Type: Periodic PT Report Source Product Alopecia Depression Nec Report Type: Periodic Report Type: Periodic PT Report Source Product Health Professional Accutane Report Type: Periodic PT Report Source Product Health Professional Accutane Report Type: Periodic PT Report Source Product Health Professional Accutane	Major Depressive Disorder Nos Health Professional Accutane SR Number: 853380-8 Report Type: Periodic Company Report Number: 853380-8 Report Type: Periodic Product Confusion Health Professional Accutane Dizziness (Exc Vertigo) Dry Eye Nee Vision Abnormal Nee SR Number: 853392-4 Report Type: Periodic Company Report Number: 853392-4 Report Source Product Alopecia Health Professional Accutane BR Number: 853529-7 Report Type: Periodic Company Report Number: 853529-7 Report Source Product Emotional Disturbance Nos Health Professional Accutane SR Number: 853544-3 Report Type: Periodic Company Report Number: Report Source Product Accutane R Number: 853544-3 Report Source Product Accutane R Number: 853544-3 Report Source Product Accutane R Number: Report Source Product Accutane	Major Depressive Disorder Nos Health Professional Accutane Product PS SR Number: 853380-8 Report Type: Periodic Company Report Number: 910200 PT Report Source Product PS Dizziness (Exc Vertigo) PS Dizziness (Exc Vertigo) PS Dizziness (Exc Vertigo) Pry Eye Nec Vision Abnormal Nec SR Number: 853392-4 Report Type: Periodic Company Report Number: 910200 PT Report Source Product Role Accutane PS Role Alopecia Health Professional Accutane PS RNumber: 853529-7 Report Type: Periodic Company Report Number: 910200 PT Report Source Product Role Emotional Disturbance Nos Health Professional Accutane PS RNumber: 853544-3 Report Type: Periodic Company Report Number: 9102005 RNumber: 853544-3 Report Type: Periodic Accutane Role Accutane Role Company Report Number: 9102005 RNumber: 853544-3 Report Type: Periodic Accutane Role PT Report Source Product Role Accutane Role	Major Depressive Disorder Nos Health Professional Accutane Product PSR Number: 853380-8 Report Type: Periodic Company Report Number: 910200981001 PT Report Source Product PS Roche Manufacturer PS Roche Product PS Roche Accutane PS Roche Manufacturer Product Role Manufacturer PS Roche Manufacturer PS Roche	Major Depressive Disorder Nos Health Professional Accutane Product PS Roche ORAL SR Number: 853380-8 Report Type: Periodic Company Report Number: 910200521011 Age: 34 YR PT Report Source Product PS Roche ORAL Dizziness (Exc Vertigo) Dry Eye Nec Vision Abnormal Nec SR Number: 853392-4 Report Type: Periodic Company Report Number: 910200708001 Age: 15 YR PT Report Source Product Role Manufacturer Route PS Roche ORAL Accutane PS Roche ORAL Company Report Number: 91020050001 Age: 23 YR PT Report Source Product Role Manufacturer Route FR Number: 853529-7 Report Type: Periodic Company Report Number: 91020050001 Age: 23 YR FT Report Source Product Role Manufacturer Route Emotional Disturbance Nos Health Professional Accutane PS Roche ORAL RNumber: 853544-3 Report Type: Periodic Company Report Number: 910200526001 Age: 41 YR PT Report Source Product Role Manufacturer Route Emotional Disturbance Nos Health Professional Accutane PS Roche ORAL Accutane Product Role Manufacturer Route Accutane PS Roche ORAL Accutane PS Roche ORAL Accutane PS Roche ORAL	Product Role Manufacturer Rout Dose/Unit

	and the second	FDA	111000	e Escal Report	111.55				
			reston	Officerossion	(BO)	Report			
Date: 06/18/1992	ISR Number: 853545-5	Report Type: Periodic		Company Report Numb	er: 910200	530001	Age: 16 YR	Con	nder: Male
Outcome Other	PT Anxiety Nec Blood Creatine Phosphokinase Increased Dysautonomia Hypoglycaemia Nos	Report Source Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration 95
Date: 06/18/1992	ISR Number: 853565-0	Report Type: Periodic		Company Report Numb	er: 910200	592001	Age: 39 YR		
Outcome Other	PT Condition Aggravated Depression Nec Insomnia Nec	Report Source Health Professional	Product Accutane Prozac		Role PS C	Manufacturer Roche	Route	Dose/Unit	Duration 32
Date: 06/18/1992	Libido Increased ISR Number: 853566-2	Report Type: Periodic		Company Report Number	er: 910200	593001	Age: 17 YR		
Outcome Other	PT Depression Nec Tooth Discolouration	Report Source Health Professional	Product Accutane Prednisone		Role PS C	Manufacturer Roche	Route	Dose/Unit	Duration 243
Date: 06/18/1992	ISR Number: 853719-3	Report Type: Periodic		Company Report Number		72001	Age: 16 YR	Gen	der: Female
Outcome Other	Emotional Disturbance Nos Hyperlipidaemia Nos	Report Source Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration
Date: 06/18/1992 Outcome	ISR Number: 854569-4	Report Type: Periodic		Company Report Numbe	r: 9102007	72001	Age: 38 YR	Gen	der: Female
Other	Arthralgia Depression Nec Emotional Disturbance Nos Vaginal Discharge	Report Source Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration 148
Date: 06/18/1992 Outcome	ISR Number: 855186-2 PT	Report Type: Periodic		Company Report Number	r: 9102009	73001	Age: 16 YR	Gene	der: Male
Other	Emotional Disturbance Nos	Report Source Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 138
Date: 08/04/1992 Outcome	ISR Number: 863294-5 PT	Report Type: Expedited (1	•	Company Report Number	r: 9202011	58001	Age: 13 YR	Gene	ler: Female
Hospitalization - Initial or Prolonged	Asthenia Confusion	Report Source Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration 42
08/03/2000				·			P	age 76	of 487

DA - Adverse Event Reporting System (Presion Of Information (FCI) Repor Date: 10/20/1992 ISR Number: 888717-7 Report Type: Expedited (15-Day) Company Report Number: 920400268001 Age: Gender: Unknown Outcome Report Source Role Hospitalization -Psychotic Disorder Nos Manufacturer Route Dose/Unit Duration Poreign Initial or Prolonged Roaccutane PS Roche ORAL Health Professional Date: 10/15/1992 ISR Number: 889484-3 Report Type: Expedited (15-Day) Company Report Number: 920201380001 Age: 21 YR Gender: Male Outcome Report Source Role Hospitalization -Major Depressive Disorder Nos Manufacturer Route Dose/Unit Duration Health Professional Accutane Initial or Prolonged PS ORAL 61 Date: 10/28/1992 ISR Number: 898067-0 Report Type: Direct Company Report Number: U015635 Age: 16 YR Gender: Male Outcome Report Source Product Role Appetite Increased Manufacturer Route Dose/Unit Duration Accutane Dianhoea Nos PS ORAL Drug Withdrawal Syndrome Personality Disorder Nos Date: 10/28/1992 ISR Number: 898117-1 Report Type: Expedited (15-Day) Company Report Number: 920400247001 Age: 22 YR Gender: Female Outcome Report Source Product Hospitalization -Depression Nec Role Manufacturer Dose/Unit Duration Route Foreign Initial or Prolonged Roaccutane Hallucination Nos PS Roche ORAL Health Professional Schizophrenia Nos Date: 10/28/1992 ISR Number: 905866-5 Report Type: Expedited (15-Day) Company Report Number: 920151009001 Age: 58 YR Gender: Male Outcome Report Source Product Hospitalization -Cheilitis Role Manufacturer Route Dose/Unit Duration Foreign Initial or Prolonged Roferon-A Confusion PS Roche SUBCUTAN Study Hallucination Nos EOUS Roaccutane SS Roche Sepsis Nos Cytotec С Senokot С Naprosyn C Date: 12/21/1992 ISR Number: 912122-8 Report Type: Expedited (15-Day) Company Report Number: 920201903001 Age: Gender: Female Outcome Report Source Product Hospitalization -Back Pain Dose/Unit Duration Health Professional Initial or Prolonged Accutane Cyst Nos. PS Roche ORAL 2 Depression Nec Leucocytosis Nos

Date: 01/21/1993	ISR Number: 914896-9	Report Type: Expedited		Fit Information						
Outcome Hospitalization - Initial or Prolonged	PT Psychotic Disorder Nos	Report Source Health Professional	Product Accutane	Company Report Numb	Role	Manufacturer	Age: 27 YR Route	Ger Dose/Unit	nder: Female Duration	
Date: 01/26/1993	ISR Number: 927191-9	Day of the control of	Excedrin		PS C	Roche	ORAL		. 5	
Outcome	PT	Report Type: Expedited		Company Report Numb	er: 920200	0661001	Age: 37 YR	Ger	nder: Female	
Disability	Agitation Convulsions Nos Thinking Abnormal Nec Thyroid Disorder Nos	Health Professional	Accutane Accutane		PS	Manufacturer Roche	Route	Dose/Unit	Duration 119	
Date: 02/03/1993	ISR Number: 928856-5	Report Type: Expedited (15-Day)	Company Report Numbe	030400					
Outcome Death	PT Anxiety Nec	Report Source	Product		Role	Manufacturer	Age: 18 YR		der: Male	ĺ
Life-Threatening	Hypothermia Overdose Nos Suicide Attempt	Foreign Health Professional	Roaccutane Alcohol		PS C	Roche	Route ORAL	Dose/Unit	Duration 74	
Date: 06/03/1991	ISR Number: 929064-4	Report Type: Direct		Company Report Number						
Outcome Death	PT Depression Nec	Report Source	Product		Role	Manufacturer	Age: 18 YR		der: Male	
Pate: 02/17/1993	ISR Number: 931094-3	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration 98	
Outcome	PT	Report Type: Expedited (1 Report Source		Company Report Number	: 9304000	028001	Age: 39 YR	Gen	der: Male	
	Cyst Nos Depression Nec	Foreign	Product Roaccutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration	
ate: 02/17/1993	Dry Skin	Health Professional				AOGIE.	ORAL.		183	
utcome	ISR Number: 931095-5	Report Type: Expedited (19 Report Source		Company Report Number	: 9201006	45001	Age: 13 YR	Geno	ler: Female	
ospitalization - itial or Prolonged	Apathy Electroencephalogram Abnormal Sedation	Foreign Health Professional	Product Roaccutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration	
	Tremor Nec				-			•		. [

				Of Information		Report			
Date: 02/17/1993 Outcome	ISR Number: 931096-7	Report Type: Expedite	ed (15-Day)	Company Report Number	r: 93031	8887001	Age:	Ge	nder: Female
Death	PT Spirit Am	Report Source	Product		D.1.		_	Ga	ider: remale
Disability	Suicide Attempt	Foreign	Roaccutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
Disability		Health Professional			гэ	Roche	ORAL		
Date: 02/24/1993	ISR Number: 933530-5	Report Type: Expedite	4/1570						
Outcome	PT	Pore Type: Expende	u (13-Day)	Company Report Numbe	r: 930200	0278001	Age: 40 YR	Ger	nder: Female
Hospitalization -	Palpitations	Report Source	Product		Role	Manufacturer	D4		
Initial or Prolonged	Supraventricular Tachycardia	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
Other	Vasodilatation					Roche	ORAL		161
Date: 04/07/1993	ISR Number: 945923-0			· · · · · · · · · · · · · · · · · · ·					
Outcome		Report Type: Expedited	đ (15-Day)	Company Report Numbe	r: 930100	007701	Age: 21 YR		1
Hospitalization -	PT	Report Source	Product					Gen	ider: Male
riospitatization - Initial or Prolonged	Amnesia Nec Anxiety Nec	Foreign	Roaccutane		Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Depression Nec	Health Professional			PS	Roche			
	Vertigo Nec		•			•			
Pate: 03/17/1993	ISR Number: 946287-9	P- 48 -							
Outcome		Report Type: Expedited	I (15-Day)	Company Report Number	: 930100	081001	Age: 24 YR	Gen	
Disability	PT Amnesia Nec	Report Source	Product		n.ı.	36		Gen	der: Female
- naning	Asthenia	Foreign	Roaccutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
	Confusion	Health Professional			rs	Roche		•	•
	Depression Nec								
nte: 03/24/1993	ISR Number: 946384-8	P					<u></u>		
outcome		Report Type: Expedited	(15-Day)	Company Report Number	930200	382001	Age:	Gen	day D 1
lospitalization -	Approximate A	Report Source	Product		D-1-			Gui	der: Female
itial or Prolonged	Aspartate Aminotransferase Increased	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
	Delusion Nos				15	Roche	ORAL		150
	Hyperlipidaemia Nos								
ite: 06/02/1993	ISR Number: 972064-9	Report Type: Expedited	(15 Der.)						
utcome	РТ		(13-Day)	Company Report Number	9302008	355001	Age: 18 YR	Gend	ler: Female
ospitalization -	Agitation	Report Source	Product		Role	Manufacturer	Route		
itial or Prolonged	Emotional Disturbance Nos	Study	Accutane		PS	Roche		Dose/Unit	Duration
	Mania	Health Professional	Benadryl		С		ORAL,	G	10
	Nervousness		Eskalith		С				
			Trilafon		С				
			Triphasil		c				

			10000	e Event Report Of Information					
Date: 06/04/1993	ISR Number: 973188-2	Report Type: Expedited		2.2					
Outcome	PT		(13-Day)	Company Report Numb	ber: 93020	0913001	Age: 31 YR	Gen	ider: Male
Death	Insomnia Nec	Report Source	Product		Role	Manufacturer			
	Pain Nos	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
	Suicide Attempt		Liver		C	Rodie	ORAL,		92
			Iron		c.				
Date: 06/21/1993	ISR Number: 978237-3	Report Type: Periodic					 		
Outcome	PT			Company Report Numb	er: 930200	0233001	Age: 33 YR	Gen	der: Female
Hospitalization -	Depression Nec	Report Source	Product		Role	Manufacturer	Danie	YS	_
Initial or Prolonged		Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
			Asendin		c	ROLLE	ORAL		32
			Tegretol		C				
			Trilafon		. C				
Date: 06/21/1993	ISR Number: 978238-5	Report Type: Periodic							
Outcome	PT			Company Report Numb	er: 930200	859001	Age: 17 YR	Gen	der: Male
Disability	Acne Nos	Report Source	Product		Role	Manufacturer	Danis	D #1.	
, ,	Condition Aggravated	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
	Depression Nec					KOLIE	ORAL		29
<u>-</u>	Skin Disorder Nos								
Date: 06/21/1993	ISR Number: 978239-7	D							
Outcome		Report Type: Periodic		Company Report Number	er: 930200	064001	Age: 21 YR	Gene	
Disability	PT	Report Source	Product					Gene	der: Female
-	Alopecia Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Hypercholesterolaemia				PS	Roche	ORAL.		123
	Infection Nos								
Pate: 06/21/1993	ISR Number: 978240-3		<u> </u>						
	20ж ишпрег: 9/8240-3	Report Type: Periodic		Company Report Number	er: 920200	353001			
Outcome	PT	Report Source	Dundand	-, - <u> </u>		-55001	Age: 16 YR	Gend	ler: Male
lospitalization -	Depression Nec	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
nitial or Prolonged Other	Emotional Disturbance Nos	Totogrand	Accutane		PS	Roche	ORAL		62
	Mania	·							02
ate: 06/21/1993	ISR Number: 978241-5	Report Type: Periodic		C					
utcome	PT			Company Report Number	r: 9302004	140001	Age: 20 YR	Gend	ier: Female
ospitalization -	Major Depressive Disorder Nos	Report Source	Product		Role	Manufacturer	Route	Dan-175-4	
itial or Prolonged	Melanodermia	Health Professional	Accutane		PS	Roche		Dose/Unit	Duration
ther							ORAL		21

Date: 06/21/1993	ISR Number: 978242-7		et erelon	se Event Report Of Information	(0.0)	Report			
Outcome	PT	Report Type: Periodic		Company Report Numb	er: 92020	1786001	Age:	G	ender: Unknown
Hospitalization - Initial or Prolonged	Depression Nec	Report Source Health Professional	Product Accutane		Role	Manufacturer	Route	Dose/Unit	
Date: 06/24/1993	ISR Number: 979354-4		Accutane		PS	Roche	ORAL		14
Outcome	РТ	Report Type: Periodic		Company Report Numb	er: 92020	688001	Age: 16 YR		ender: Male
Other	Dermatitis Nos	Report Source Health Professional	Product Accutane		Role	Manufacturer	Route	Dose/Unit	
	Drug Withdrawal Syndrome Hostility Nervousness		Augmentin		PS C	Roche	ORAL		63
Date: 06/24/1993	ISR Number: 979379-9	Report Type: Periodic		Communa				-	
Outcome	PT PT	Report Source	Product	Company Report Numb		856001	Age: 15 YR	Ge	ender: Male
ound.	Emotional Disturbance Nos Influenza Like Illness	Health Professional	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
<u> </u>	Personality Disorder Nos Rhinitis Nos			v *			ORAL		.8
Date: 06/24/1993	ISR Number: 979389-1	Report Type: Periodic							
Outcome	PT Agitation	Report Source	Product	Company Report Number			Age: 27 YR	Ger	nder: Pemale
oui <u>u</u>	Agitation Cystitis Nos	Health Professional	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
	Menometronhagia		Azo Gantrisi Ortho-Novu		C		ORAL		15
Date: 06/24/1993			Klonopin	m ////	C .				
Outcome	ISR Number: 979390-8	Report Type: Periodic	i ia	Company Report Number		23001			
Other	PT Dysphonia	Report Source	Product		Role	Manufacturer	Age: 15 YR		nder: Female
-	Hypersensitivity Nos Laryngeal Neoplasm Nos Rhinitis Nos	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
ate: 06/24/1993	ISR Number: 979391-X	Report Type: Periodic							
utcome	PT	Report Source		Company Report Number	92020082	27001	Age: 19 YR	Gen	der: Male
ther	Impotence	Health Professional	Product		Role	Manufacturer	Route		j

Dysphonia	Health Professional	Troubet		Role	Manufacturer	Route	Dose/Unit	Duration
PT	Report Source	Product				6	Gena	ler: Female
ISR Number: 979870-5	Report Type: Periodic		Company Report Number	er: 9202012	03001	Age: 33 YR	G	lam. Para I
Hyperphosphataemia								
Decreased						UKAL		98
• •	Health Professional	Accutane		PS	Roche		Dose/Unit	Duration
	Report Source	Product		Role	Manufacturer	-		- Tomalo
ISR Number: 979869-9	Report Type: Periodic		Company Report Number	er: 9202012	02001	Age: 20 YR	Genri	ler: Female
Libido Decreased	ricalth Professional	Accutane		PS	Roche	ORAL		1
	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	· ·		Company Report Numb	er: 9202011	35001	Age: 25 YR	Gene	der: Male
	D			<u> </u>			_	
Condition Aggravated Depression Nec	Introdecator in	Accutane		PS	Roche	ORAL		137
Acne Nos				Role	Manufacturer	Route	Dose/Unit	Duration
PT			Company Report Numb	er: 9202010	012001	Age: 17 YR	Gene	der: Male
ISR Number: 979425-2	Report Type: Periodic					·	·····	
Depression Nec Emotional Disturbance Nos				rə	Koche	ORAL		92
Alopecia	Health Professional		<u> </u>		Manufacturer	Route	Dose/Unit	Duration
PT	Report Source	Product	- Family medical tanking			Age: 30 YR	Gen	der: Pemale
ISR Number: 979418-5	Report Type: Periodic		Company Report Numb	920200	754001			 -
Libido Decreased								
Endocrine Disorder Nos	readul Professional	Accutane		PS	Roche	ORAL		162
Asthenia		Product		Role	Mannfacturer	Route	Dose/Unit	Duration
	Report Type: Periodic		Company Report Numb	er: 920200	792001	Age: 60 YR	Gen	der: Male
				PS	Koche	ORAL		
Amnesia Nec	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration
PT		D	Company Report Attini	ner: 920200	821001	Age:	Gen	der: Male
ISR Number: 979393-3	Report Type: Periodic		Company Panort Name	000000	201001			
					i Kepart			
	PT Amnesia Nec Headache Nos ISR Number: 979400-8 PT Asthenia Endocrine Disorder Nos Homnone Level Nos Abnormal Libido Decreased ISR Number: 979418-5 PT Alopecia Depression Nec Emotional Disturbance Nos ISR Number: 979425-2 PT Acne Nos Condition Aggravated Depression Nec ISR Number: 979447-1 PT Impotence Libido Decreased ISR Number: 979869-9 PT Dysphonia High Density Lipoprotein Decreased Hyperlipidaemia Nos Hyperphosphataemia ISR Number: 979870-5	ISR Number: 979393-3 Report Type: Periodic PT Armesia Nec Health Professional Health Professional Report Source Health Professional Report Source Health Professional Report Type: Periodic PT Report Source Health Professional Report Source Health Professional Report Type: Periodic Report Source Health Professional Report Type: Periodic Report Source Health Professional Report Type: Periodic Report Source Health Professional Report Type: Periodic PT Report Source Health Professional Report Type: Periodic Health Professional Report Type: Periodic Report Source Health Professional Report Type: Periodic Report Source Health Professional Report Source Health Professional Report Type: Periodic Report Source Health Professional Report Source Health Professional Report Type: Periodic Report Source Health Professional Report Source Health Professional Report Type: Periodic Report Source Health Professional Report Type: Periodic	ISR Number: 979393-3 Report Type: Periodic PT Report Source Health Professional Accutance Report Type: Periodic Report Source Product Health Professional Accutance Report Source Product Ashenia Endocrine Disorder Nos Homnone Level Nos Abnormal Libido Decreased ISR Number: 979418-5 Report Type: Periodic PT Report Source Health Professional Accutance Product Alopecia Depression Nec Emotional Disturbance Nos ISR Number: 979425-2 Report Type: Periodic PT Report Source Health Professional Accutance Product Accutance Product Anne Nos Condition Aggravated Depression Nec ISR Number: 979447-1 Report Source Product Isr Number: 979447-1 Report Source Product Isr Number: 979869-9 Report Type: Periodic PT Report Source Health Professional Accutance ISR Number: 979869-9 Report Type: Periodic Product Health Professional Accutance Product Health Professional Accutance Health Professional Accutance Product Health Professional Accutance Product Health Professional Accutance Product Health Professional Accutance Product Product Product Product Propertional Health Professional Report Type: Periodic Propertional Health Professional Report Type: Periodic Propertional Health Professional Report Type: Periodic Propertional Report Source Product Product Propertional Report Source Product Propertional Report Type: Periodic Propertional Report Type: Periodic Propertional Report Type: Periodic	ISR Number: 979393-3 Report Type: Periodic PT Report Source Health Professional Accutane Report Type: Periodic Arcutane Report Source Product Accutane Report Source Product Accutane Report Source Product Asthenia Endocrine Disorder Nos Hormone Level Nos Abnormal Libido Decreased ISR Number: 979418-5 Report Type: Periodic Report Source Product Accutane PT Report Source Accutane Product Accutane Product Accutane Report Source Emotional Disturbance Nos ISR Number: 979425-2 Report Type: Periodic Company Report Numb Report Source Health Professional Depression Nec Condition Aggravated Depression Nec ISR Number: 979447-1 Report Source Health Professional Report Source Health Professional Report Source Health Professional Accutane Company Report Numb Report Source Product Accutane Company Report Numb Report Source Product Accutane Company Report Numb Report Source Product Accutane Impotence Libido Decreased Report Type: Periodic Company Report Numb PT Report Source Product Accutane Libido Decreased Report Type: Periodic Accutane ISR Number: 979869-9 Report Type: Periodic Accutane PT Report Source Product Accutane Libido Decreased Report Source Product Accutane Libido Decreased Report Source Product Accutane Accutane Libido Decreased Report Source Product Accutane Libido Decreased Report Source Product Accutane Accutane Accutane Libido Decreased Report Source Product Accutane Accutane Accutane Accutane Company Report Number PT Report Source Product Accutane Accutane Accutane Accutane Company Report Number PT Report Source Product Accutane Company Report Number PT Report Source Accutane Company Report Number	ISR Number: 979393-3 Report Type: Periodic PT Report Source Health Professional Report Source PT Report Source PT Report Source Health Professional Report Type: Periodic Report Source Health Professional Report Source PT Report Source PT Report Source Report Source PT Report Source Report Source Emotional Distribunce Nos Report Type: Periodic Report Source Product Role Report Source Product Role Report Source Report Source Product Role Report Source Report Source Product Role Report Source Report Source Report Source Product Role Report Source Report Source Report Source Role Report Source Report	PT	PT	SER Number: 979393-3 Report Type: Periodic Campany Report Number: 920200821001 Age: Dose/Unit

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Date: 06/24/1993	ISR Number: 979875-4	Report Type: Periodic		Company Report Numb			Age: 35 YR			
Outcome	PT	Report Source	Dan dan d				Age: 35 YR	Ge	nder: Male	
Other	Hyperlipidaemia Nos	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Impotence	ricalar i fotessional	Accutane		PS	Roche	ORAL		28	•
	Myalgia								20	
Date: 06/24/1993	ISR Number: 979889-4	Report Type: Periodic		Company Report Number	r: 920200	676001	Age: 17 YR			_
Outcome	PT	Report Source	Dundant	_			Age: 1/ IK	Ger	nder: Male	
Other	Depression Nec	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Dry Mouth		Accutane		PS	Roche	ORAL	,	378	
	Sédation		Vitamins		C				210	
Date: 06/24/1993	ISR Number: 979907-3	Report Type: Periodic		Company Report Numbe	r: 920200	618001	Age: 15 YR		ıder: Male	
Outcome	PT	Report Source	Product					Ga	ıder: Male	
Other	Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
<u> </u>	Nail Disorder Nos Personality Disorder Nos		recolane		PS	Roche	ORAL		42	
Date: 06/24/1993	ISR Number: 979926-7	Report Type: Periodic		Company Report Numbe	920201	126001	4			
Outcome	_ PT	Report Source	D			.50001	Age:	Gen	der: Female	
Other	Asthenia	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Depression Nec	A South I Toressional	Accutane		PS	Roche	ORAL		152	
	Headache Nos	,							132	•
	Systemic Lupus Erythematosus									
Date: 06/24/1993	ISR Number: 980368-9	Report Type: Periodic		C		-				
Outcome	PT	17.0		Company Report Number	9202018	36001	Age: 17 YR	Gen	der: Male	
Other	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Desert Inde		
	Emotional Disturbance Nos	Health Professional	Accutane		PS	Roche		Dose/Unit	Duration	
			Minocin		Ċ		ORAL		66	
Date: 06/24/1993	ISR Number: 980369-0	Report Type: Periodic				·	· · · · · · · · · · · · · · · · · · ·			
Outcome	PT			Company Report Number	9202018	36002	Age: 15 YR	Gen	der: Male	
Other	Agitation	Report Source	Product		Role	Manufacturer	Route	D		
	Albuminuria Present	Health Professional	Accutane		PS	Roche		Dose/Unit	Duration	
	Anaemia Nos		Minocin		c	- wellt	ORAL		14	
	Depression Nec				~					

		I	reignom	e Event Reporti Of Information		Reput				
Date: 06/24/1993	ISR Number: 980373-2	Report Type: Periodic		Company Report Number	er: 92020	1890001	Age: 26 YR	Gene	der: Female	
Other Other	Emotional Disturbance Nos	Report Source Health Professional	Product Accutane Premarin		Role PS C	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 21	
Date: 06/24/1993	ISR Number: 980793-6	Report Type: Periodic		Company Report Number		1519001	Age: 30 YR	Gene	ler: Female	
Outcome	PT Alopecia Anxiety Nec Eye Pain Simusitis Nos	Report Source Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 6	
Date: 06/24/1993	ISR Number: 980817-6	Report Type: Periodic		Company Report Numbe	r: 920201	100988	Age: 16 YR	Gend	ler: Male	
Other	PT Emotional Disturbance Nos Thinking Abnormal Nec	Report Source Health Professional	Product Accutane Bactroban	<u> </u>	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 141	
Date: 06/24/1993 Outcome	ISR Number: 980820-6 PT	Report Type: Periodic		Company Report Numbe		134001	Age: 16 YR	Gend	ler: Male	
Disability	Anxiety Nec Blindness Night Personality Disorder Nos	Report Source Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration 73	
Date: 06/24/1993 Outcome	ISR Number: 980824-3	Report Type: Periodic Report Source		Company Report Number	r; 930200	053001	Age: 15 YR	Gend	er: Female	
Life-Threatening	Condition Aggravated Major Depressive Disorder Nos Suicide Attempt	Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration	
Date: 06/24/1993	ISR Number: 980828-0	Report Type: Periodic		Company Report Number	: 920201	984001	Age: 17 YR	Gend	er: Male	
Outcome Hospitalization - Initial or Prolonged	PT Dry Mouth Dry Skin Emotional Disturbance Nos	Report Source Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration 140	
Date: 06/24/1993	Major Depressive Disorder Nos ISR Number: 980830-9	Report Type: Periodic		Company Report Number	. 020201	Degraph.				
Outcome	PT	Report Source	Product	Land webove (4mmpe)			Age: 14 YR	Gende	r: Female	
Disability	Dizziness (Exc Vertigo)	Health Professional	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration	

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Rep Rep	port Type: Periodic Report Source Tealth Professional port Type: Periodic Report Source Consumer port Type: Periodic Report Source Lealth Professional port Type: Periodic Report Source Lealth Professional port Type: Periodic Report Source Lealth Professional	Product Accutane Product Accutane Product Accutane Product Accutane Product Accutane Product Accutane Product Accutane	Company Report Numb Company Report Numb Company Report Numb Company Report Numbe	Role PS PS Role PS Role PS Role PS Role PS C C	Manufacturer Roche 727001 Manufacturer Roche 933001 Manufacturer Roche 939001 Manufacturer Roche	Age: Rout ORA Age: Rout ORA Age: Rout ORA Age: Rout ORA	17 YR ste	Dose/Unit Gen Dose/Unit Gen Dose/Unit	nder: Ma Duration 21 Ider: Fee Duration 366 Ider: Ma Duration 67 Ider: Ma Duration 67	male male male male male male male male
Rep Rep	port Type: Periodic Report Source	Product Accutane Product Accutane Product Accutane Product Accutane	Company Report Number Company Report Number Company Report Number	Role PS C	Manufacturer Roche 727001 Manufacturer Roche 033001 Manufacturer Roche 039001 Manufacturer Roche	Age: Rout ORA Age: Rout ORA Age: Rout ORA Age: Rout ORA	17 YR	Dose/Unit Gen Dose/Unit Gen Dose/Unit	Duration 164 Duration 164 Duration 164	male male male male
Rep Rep	port Type: Periodic Report Source Health Professional port Type: Periodic Report Source Consumer port Type: Periodic Report Source Lealth Professional	Product Accutane Product Accutane Product Accutane Product Accutane	Company Report Numb	Role PS	Manufacturer Roche 727001 Manufacturer Roche 033001 Manufacturer Roche 039001 Manufacturer	Age: Rom ORA Age: Rom ORA Age: Rom Age: Rom ORA	17 YR 1 AL 27 YR 1 AL 22 YR 1 AL 22 YR 22 YR 22 YR 24 YR 24 YR 25 YR 26 YR 2	Gen Gen Gen	Duration 21 Duration 366 dder: Ma Duration 164 Duration	male male male
Rep Rep	port Type: Periodic Report Source Health Professional port Type: Periodic Report Source Consumer port Type: Periodic Report Source Lealth Professional	Product Accutane Product Accutane Product Accutane Product Accutane	Company Report Numb	Role PS	Manufacturer Roche 727001 Manufacturer Roche 033001 Manufacturer Roche 039001 Manufacturer	Age: Rom ORA Age: Rom ORA Age: Rom Age: Rom ORA	17 YR 1 AL 27 YR 1 AL 22 YR 1 AL 22 YR 22 YR 22 YR 24 YR 24 YR 25 YR 26 YR 2	Gen Gen Gen	Duration 21 Duration 366 dder: Ma Duration 164 Duration	male male male
Rep Rep	port Type: Periodic Report Source Health Professional port Type: Periodic Report Source Consumer port Type: Periodic Report Source Lealth Professional	Product Accutane Product Accutane Product Accutane	Company Report Numb	Role PS Role PS Role PS Role PS Role PS Role PS Role Role PS Role Role Role	Manufacturer Roche 727001 Manufacturer Roche 033001 Manufacturer Roche 039001 Manufacturer	Age: Rom ORA Age: Rom ORA Age: Rom Age: Rom ORA	17 YR 1 AL 27 YR 1 AL 22 YR 1 AL 22 YR 22 YR 22 YR 24 YR 24 YR 25 YR 26 YR 2	Gen Gen Gen	Duration 21 Duration 366 dder: Ma Duration 164 Duration	male male male
980838-3 Rep Rec H 980851-6 Rep 980861-9 Rep Rr Nos 180864-4 Rep Re	port Type: Periodic Report Source Health Professional port Type: Periodic Report Source Consumer port Type: Periodic Report Source Lealth Professional	Product Accutane Product Accutane Product Accutane	Company Report Numb	Role PS Role PS Role PS Role PS Role PS er: 92020073 Role PS er: 92020103	Manufacturer Roche 727001 Manufacturer Roche 033001 Manufacturer Roche	Age: Rom ORA Age: Rom ORA Age: Rom Age: Age:	17 YR	Gen Gen Gen	Duration 21 Duration 366 dder: Ma Duration 164	male male male
Rep Rep	port Type: Periodic Report Source Health Professional port Type: Periodic Report Source Consumer Port Type: Periodic Report Source Legith Professional port Type: Periodic	Product Accutane Product Accutane Product	Company Report Numb	Role PS	Manufacturer Roche 727001 Manufacturer Roche 333001 Manufacturer Roche	Age: Rou ORA Age: Rou ORA Age: Rou ORA	17 YR	Dose/Unit Gen Dose/Unit	Duration 366 Duration 366 Duration 164	ale male male male male male male male m
980838-3 Rep	port Type: Periodic Report Source Tealth Professional port Type: Periodic Report Source Consumer port Type: Periodic	Product Accutane Product Accutane Product	Company Report Numb	Role PS Role PS Role PS Role PS Role Role Role Role Role	Manufacturer Roche 727001 Manufacturer Roche 033001 Manufacturer	Age: Rou ORA Age: Rou ORA Age: Rou Rou	17 YR tte 1 27 YR 27 YR L 22 YR tte 1	Dose/Unit Gen Dose/Unit	Duration 21 Duration 366 der: Ma	ale male male
980838-3 Rep Rec H 980851-6 Rep 600 C 980861-9 Rep Rep Rep H r Nos	port Type: Periodic Report Source Tealth Professional port Type: Periodic Report Source Consumer port Type: Periodic	Product Accutane Product Accutane Product	Company Report Numb	Role PS Role PS Role PS Role PS Role Role Role Role Role	Manufacturer Roche 727001 Manufacturer Roche 033001 Manufacturer	Age: Rou ORA Age: Rou ORA Age: Rou Rou	17 YR tte 1 27 YR 27 YR L 22 YR tte 1	Dose/Unit Gen Dose/Unit	Duration 21 Duration 366 der: Ma	ale male male
Rep Pec	port Type: Periodic Report Source Tealth Professional port Type: Periodic Report Source Consumer port Type: Periodic	Product Accutane Product Accutane Product	Company Report Numb	Role PS Role PS Role PS Role PS Role Role Role Role Role	Manufacturer Roche 727001 Manufacturer Roche 033001 Manufacturer	Age: Rou ORA Age: Rou ORA Age: Rou Rou	17 YR tte 1 27 YR 27 YR L 22 YR tte 1	Dose/Unit Gen Dose/Unit	Duration 21 Duration 366 der: Ma	ale male male
980838-3 Rep Rec H 980851-6 Rep C C 980861-9 Rep Re	port Type: Periodic Report Source Tealth Professional port Type: Periodic Report Source Consumer port Type: Periodic	Product Accutane Product Accutane Product	Company Report Numb	PS Role PS PS PS PS PS PS PS PS PS	Manufacturer Roche 727001 Manufacturer Roche 033001	Age: Ron ORA Age: Row ORA Age:	17 YR] AL 27 YR] AL 22 YR	Dose/Unit Gen Dose/Unit	Duration 21 Duration 366 Ms	ale male male
980838-3 Rep Rec H 980851-6 Rep C C 980861-9 Rep	port Type: Periodic Report Source Health Professional port Type: Periodic Report Source Consumer	Product Accutane Product Accutane	Company Report Numb	Role PS PS Role PS PS	Manufacturer Roche 727001 Manufacturer Roche	Age: Ron Age: Ron ORA	17 YR AL 27 YR tte 1	Dose/Unit Gen Dose/Unit	Duration 21 Duration 21 Duration 366	iale on male
980838-3 Rep Rec H 980851-6 Rep Cc C	port Type: Periodic Report Source	Product Accutane Product	Company Report Numb	Role PS PS Role PS PS	Manufacturer Roche 727001 Manufacturer Roche	Age: Ron Age: Ron ORA	17 YR AL 27 YR tte 1	Dose/Unit Gen Dose/Unit	Duration 21 Duration 21 Duration 366	ale on emale
980838-3 Rep Rec H 980851-6 Rep	port Type: Periodic Report Source Health Professional port Type: Periodic Report Source	Product Accutane Product		Role PS PS Role Role PS	Manufacturer Roche 727001 Manufacturer	Age: Ron ORA Age:	17 YR tte]	Dose/Unit Gen	Duration 21 Duration Duration	ale on emale
980838-3 Rep Rep (ec H 980851-6 Rep	port Type: Periodic Report Source Health Professional port Type: Periodic	Product Accutane		Role PS PS PS	Manufacturer Roche	Age: Rott ORA	17 YR tte 1 27 YR	Dose/Unit Gen	Duration 21 ader: Fer	ale on emale
980838-3 Rep	port Type: Periodic Report Source Health Professional	Accutane		PS 9302002	222001 <u>Manufacturer</u> Roche	ORA Age: Rott	17 YR	Dose/Unit	nder: Ms Duration 21	ale on
980838-3 Rep	port Type: Periodic Report Source	Accutane	Company Report Numb	per: 9302002 Role	222001 Manufacturer	ORA	17 YR		nder: Ma	[ale
980838-3 Rep	port Type: Periodic Report Source	Accutane	Company Report Numb	per: 9302002	222001	ORA	17 YR		nder: Ma	[ale
980838-3 Rep	port Type: Periodic	Accutane	Company Report Numb			ORA		Gen		
							AL		123	DIA
Syndrome	reaim riolessional			PS	Roche		AL		123	on
										on_
Land NT.	Health Professional	Product		Role	Manufacturer	Rou	ite	Dose/Unit	Duratio	
F	Report Source		* * * * * * *				24 YR	Gen	ıder: Ma	lale
980836-X Rep	port Type: Periodic		Company Report Numb	ber: 9302002	219001	A	24.WD		·	
pathy s										
os										
xc Vertigo)		-			Rocale	ORA	AL		31	
		Accutane							. ==,===	on_
	rest Type. Taronic	Tronuct	Company Report Numb					Dose/Unit	Duratio	
980830-9 Re	eport Type: Periodic	Product	Company Report Numl			Ron		Dose/Unit	Duratio	
980830-9 Re			Company Report Number	her: Bak 2019	962 Mi nufacturer			Dose/Unit	Duratio	
			c Vertigo)		sc Vertigo)	to Vertigo)	cc Vertigo)	to Vertigo) CRAL	to Vertigo) CRAL	Accutanc PS Roche ORAL 31

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				Of Information		Report			
Date: 06/24/1993	ISR Number: 981132-7	Report Type: Periodic		Company Report Numl	ber: 930200	174001	Age:	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	D#1#4	T
Other	Amblyopia Nos Emotional Disturbance Nos Headache Nos Simusitis Nos	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration 71
Date: 06/24/1993	ISR Number: 981143-1	Report Type: Periodic	·	Company Report Numb	ber: 930200	140001	Age: 32 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Dont	D 67 4	
Other	Dizziness (Exc Vertigo) Palpitations	Health Professional	Accutane		PS	Roche	Route ORAL	Dose/Unit	Duration 17
Date: 06/24/1993	ISR Number: 981213-8	Report Type: Periodic		Company Report Numb	per: 930200	402001	Age: 30 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	D#L**	D 41
Other	Asthenia Depression Nec	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration 105
Date: 06/24/1993	ISR Number: 981247-3	Report Type: Periodic		Company Report Numb	per: 9202019	96000i	Age: 36 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Personality Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL	Dospoint	121
Date: 06/24/1993	ISR Number: 981259-X	Report Type: Periodic		Company Report Numb	er: 9202018	361001	Age: 17 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	D	
Other	Arthralgia	Health Professional	Accutane		PS	Roche		Dose/Unit	Duration
	Asthenia Cheilitis Insomnia Nec						ORAL		107
Date: 06/24/1993	ISR Number: 981299-0	Report Type: Periodic		Company Report Numb	er: 9202016	544001	Age: 15 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	D4		
Other	Depression Nec	Health Professional	Accutane		PS	Roche	Route ORAL	Dose/Unit	Duration 140
Date: 06/24/1993	ISR Number: 981300-4	Report Type: Periodic		Company Report Numb	er: 9302003	319001	Age: 35 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route		A OHIMIC
Outcome								Dose/Unit	Duration

		·	e (aleman)	Officialismedia		Report			
Date: 06/24/1993	ISR Number: 981330-2	Report Type: Periodic		Company Report Numb	er: 920201	526001	Age: 18 Y	'R Ge	nder: Male
Outcome	PT	Report Source	Product		Role	Manufacturer			
Other	Depression Nec	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
	Leucopenia Nos	· · · · · · · · · · · · · · · · · · ·			10	Rocne	ORAL		28
Date: 06/24/1993	ISR Number: 981657-4	Report Type: Periodic		Company Report Numb	er: 920201	963001	Age: 30 Y	TP G-	
Outcome	_ PT	Report Source	Product				13ge: 30 I	K Ga	ider: Female
Other	Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
			Accutante		PS	Roche	ORAL		144
Date: 06/24/1993	ISR Number: 982043-3	Report Type: Periodic		Company Report Numb	er: 920201	21001	Age: 24 Y	'D C-	
Outcome	PT	Report Source	Product				_	n Ga	nder: Male
Other	Paranoia	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	•	* * ***********************************	Lithium		PS C	Roche	ORAL		15
			Navane		C				
			Thorazine		C	•			
Date: 06/24/1993	ISR Number: 982059-7	Report Type: Periodic							
O-4		Report Type: Periodic		Company Report Numb	er: 920201	545001	Age:	Ger	ider: Male
Outcome	PT Confusion	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Ouler	Depression Nec	Health Professional	Accutane		PS	Roche	ORAL		Duranon
Date: 06/24/1993	ISR Number: 982070-6		-						
		Report Type: Periodic		Company Report Numb	er: 920201	582001	Age: 29 Y	R Gen	ider: Female
Outcome	PT.	Report Source	Product		Role	Manufacturer	Route	D	
Other	Acne Nos Anxiety Nec	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	<u>Duration</u> .
	Depression Nec						ORAL		119
	Insomnia Nec						*	*	
Date: 06/24/1993	ISR Number: 982270-5	Report Type: Periodic					· · ·		
Outcome	PT			Company Report Number	er: 920201	664001	Age:	Gen	der: Male
Other	Personality Disorder Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Accutane		PS	Roche	ORAL		1
Date: 06/24/1993	ISR Number: 982892-1	Report Type: Periodic		G					
Outcome	PT			Company Report Number	er: 930200	548001	Age: -	Gen	der: Female
Other	Anxiety Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Consumer	Accutane		PS	Roche	ORAL		150
	Vaginal Candidiasis								
	Vaginitis								

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			fection	Of informatio		Report			
Date: 06/24/1993	ISR Number: 982899-4	Report Type: Periodic		Company Report Nun	ber: 930200	0631001	Age: 36 YR	G	
Outcome	PT	Report Source	Product				21ge. 30 IK	Ger	nder: Female
Other	Alopecia	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration
1	Arthralgia		Accutane		PS	Roche	ORAL		113
	Depression Nec								
	Systemic Lupus Erythematosus Rash								
Date: 06/24/1993	ISR Number: 982910-0	Report Type: Periodic							
Outcome				Company Report Num	ber: 930200	599001	Age: 17 YR	Gen	ider: Male
Other	PT Emotional Dist.	Report Source	Product		Role	Manufacturer			
Oulei	Emotional Disturbance Nos	Health Professional	Accutane		PS PS		Route	Dose/Unit	Duration
			Ritalin		rs C	Roche	ORAL	80	101
Date: 06/24/1993	ISR Number: 982959-8	D							
Outcome		Report Type: Periodic		Company Report Num	ber: 920201	067001	Age: 14 YR	Gen	ider: Male
	PT	Report Source	Product		D.1.			04	Maje
Other	Agitation	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos Insomnia Nec		····		PS	Roche	ORAL		75
Date: 06/24/1993									
00/24/1993	ISR Number: 983217-8	Report Type: Periodic		Company Report Num	her: 030200	234001			
Outcome	PT	Report Source			Dea: 330200	234001	Age: 19 YR	Gen	der: Male
Other	Aspartate Aminotransferase	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration ,
	Increased	Health Professional	Accutane		PS	Roche	ORAL		91
	Blood Lactate Dehydrogenase Increased								71
	Leucocytosis Nos								
· · · · · · · · · · · · · · · · · · ·	Palpitations								
Date: 06/24/1993	ISR Number: 983229-4	Report Type: Periodic							
Outcome		report Type: Periodic		Company Report Numb	er: 930200	564001	Age: 20 YR	Gen	der: Male
Other	PT	Report Source	Product		Dala	36			Male
лист	Alopecia Depression N	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec				PS	Roche	ORAL		140
ate: 06/24/1993	ISR Number: 983249-X	Report Type: Periodic		Common D		· · · · · · · · · · · · · · · · · · ·			
Outcome	PT			Company Report Numb	er: 9302005	514001	Age: 22 YR	Gene	der: Female
Other	Nervousness	Report Source	Product	·	Role	Manufacturer	Route	Done/I lut	D- 4
*		Foreign	Accutane		PS	Roche		Dose/Unit	Duration
		Health Professional					ORAL	80	127

Date: 06/24/1993	TOTAL .		eredou	e Event Report Of histormation		Report			
	ISR Number: 983257-9	Report Type: Periodic		Company Report Numb	er: 93020	0396001	Age: 21 YR	Ca	nder: Female
Outcome	PT	Report Source	Product				- DIIK	Ga	nuer: remale
Other	Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Dry Skin Vasodilatation		Prozac		PS	Roche	ORAL		31
	, and an analysis		Synthroid		SS	Dista Prod			
Date: 06/24/1993	ISR Number: 983262-2		Syndhold	· · · · · · · · · · · · · · · · · · ·	C				
	15K Nummer: 963262-2	Report Type: Periodic		Company Report Numb	er: 930200	0378001	Age: 16 YR		
Outcome	PT	Report Source	Product				Age. 10 IK	Ger	nder: Female
Other	Dysphonia	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration
		- Torcatolia	Accutane		PS	Roche	ORAL		160
Date: 06/24/1993	ISR Number: 983313-5	Report Type: Periodic		C					
Outcome	PT			Company Report Number	er: 930200	0104001	Age: 20 YR	Ger	nder: Female
Other	Amblyopia Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D#
	Amnesia Nec	Health Professional	Accutane		PS	Roche	ORAL	. Dosd Citt	Duration
	Conjunctivitis Nec						OKAL		31
Date: 06/24/1993	ISR Number: 983314-7	D							
Outcome		Report Type: Periodic		Company Report Number	r: 930200	112001	Age: 15 YR	Gen	ıder: Male
Other	_ <u>PT</u>	Report Source	Product		D.1.			O Can	tuer. Male
Oiner	Hostility	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
Date: 06/24/1993	Yan				PS	Roche	ORAL		2
June: 00/24/1993	ISR Number: 983799-6	Report Type: Periodic		Company Report Numbe	020201	917001			<u>:</u>
Outcome	_ PT	Dament C	_	comband sceholt (stillibe	ar: 920201	81/001	Age: 16 YR	Gen	ıder: Female
Other	Acne Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Condition Aggravated	Health Professional	Accutane		PS	Roche	ORAL		Duration
	Insomnia Nec						OKAL		
late: 06/24/1993	ISR Number: 983810-2	Depart To D. III							
Outcome		Report Type: Periodic		Company Report Numbe	r: 920201	786005	Age: 30 YR	Gen	der: Unknown
	PT	Report Source	Product					Gui	onknown
Other	Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
ate: 06/24/1993					PS	Roche	ORAL		
00/24/1993	ISR Number: 983811-4	Report Type: Periodic		Company Report Number	020201	790001			
outcome	PT	Danast C		hand rehort (4mill)	r: 920201	/ DUUVI	Age: 38 YR	Gen	der: Female
ther	Acne Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Alopecia	Health Professional	Accutane		PS	Roche	ORAL	Dun Oill	
	Dermatitis Nos						OKAL		43
	Emotional Disturbance Nos								

Date: 06/24/1993	ISR Number: 983812-6	Report Type: Periodic		Company Report Numb	r: 920201	1786002	Age:	Gend	ler: Male
Ontcome	PT	Report Source	Product						
Other	Personality Disorder Nos	Health Professional	Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration
Date: 06/24/1993	ISR Number: 984149-1	Report Type: Periodic		Company Report Numb	r: 920201	732001	Age: 35 YR	Gend	ler: Female
Outcome	PT	Report Source	Product				<u>-</u> ,		
Other	Amnesia Nec Face Oedema	Health Professional	Асситале		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
Date: 06/24/1993	ISR Number: 984150-8	Report Type: Periodic		Company Report Numb	er: 920201	715001	Age: 30 YR	Gend	ler: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	D . #7 #	•
Other	Dysphonia	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration 41
Date: 06/24/1993	ISR Number: 984173-9	Report Type: Periodic		Company Report Numb	r: 930200	1483001	Age: 15 YR	Gend	
Outcome	PT Glossitis	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Headache Nos Thinking Abnormal Nec	Health Professional	Accutane		PS	Roche	ORAL	80	112
Date: 06/24/1993	ISR Number: 984177-6	Report Type: Periodic		Company Report Number	r: 930200	470001	Age: 15 YR	Gend	ler: Male
Outcome	PT	Report Source	Product		D.1.				-21 Majo
Other	Agitation	Health Professional	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
	Hostility Personality Disorder Nos					ANALIE .	ORAL	80	94
Date: 06/24/1993	ISR Number: 984185-5	Report Type: Periodic		Company Report Number	r: 930200	430001	Age: 16 YR	Gend	er: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Demetter
Other	Alopecia Cheilitis	Consumer	Accutane		PS	Roche	ORAL	80	Duration
	Depression Nec Hyperlipidaemia Nos						ORAL	ου	116 .
Date: 06/24/1993	ISR Number: 984187-9	Report Type: Periodic		Company Report Numbe	r: 930200	422001	Age: 16 YR	Gend	er: Male
							-60 T14		
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	- HIMLO

		1	reedom	e I vent Reports Of Information		Report			
Date: 06/24/1993	ISR Number: 985064-X	Report Type: Periodic		Company Report Numbe	r: 930200	004001	Age: 27 YR	Gene	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer			_
Other	Dry Eye Nec Emotional Disturbance Nos	Health Professional	Accutane		PS	Roche	Route ORAL	Dose/Unit	Duration 10
	Skin Discolouration Taste Disturbance	<u> </u>	_						
Date: 06/24/1993	ISR Number: 985075-4	Report Type: Periodic		Company Report Number	920202	055001	Age: 21 YR	Gen	der: Male
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Ouler	Amblyopia Nos Blindness Night Depression Nec Epistaxis	Health Professional	Accutane		PS	Roche	ORAL	Dose Cint	Duration
Date: 06/24/1993									
Outcome	ISR Number: 985079-1	Report Type: Periodic		Company Report Number	920202	047001	Age: 29 YR	Gen	der: Male
Other	Personality Disorder Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	- wiscinstry Disolder Nos	Health Professional	Accutane		PS	Roche	ORAL		3165
Date: 06/24/1993	ISR Number: 985084-5	Report Type: Periodic		Company Report Number	920202	034001	Age: 32 YR	Gen	
Outcome Other	- PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Major Depressive Disorder Nos	Health Professional	Accutane Estrace		PS	Roche	ORAL	40	146
Date: 06/24/1993	ISR Number: 985088-2	Report Type: Periodic	Latace	Company Report Number	C 9202020	021001	Age: 15 YR	Gen	3 >+1
Outcome	PT	Report Source	Product					Gal	der: Male
Other	Major Depressive Disorder Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Personality Disorder Nos		Accurate		PS	Roche	ORAL		116
Dutcome	ISR Number: 985095-X	Report Type: Periodic		Company Report Number	9202010	581001	Age: 21 YR	Gen	der: Female
Hospitalization -	PT Agitation	Report Source	Product		Role	Manufacturer	Route .	Dose/Unit	Duration
nitial or Prolonged Other	Personality Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL		32
ate: 06/24/1993	ISR Number: 985102-4	Report Type: Periodic		Company Report Number	0202010	N64001	A		-
Outcome	PT	Panort Some	.	Land reshore (diffine)	202010	A-10VI	Age: 30 YR	Gen	der: Female
Disability	Abdominal Pain Nos Arthralgia	Report Source Health Professional	Product Accutane	 	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration
	Bone Pain						OKAL.		

		FDA		t Frent Repo Of Informat		tem (APRS) Record			
Date: 06/24/1993 Outcome	ISR Number: 985103-6	Report Type: Periodic		Company Report N			Age: 15 YR	Gen	der: Female
Disability	Back Pain	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Insomnia Nec	Health Professional	Accutane		PS	Roche	ORAL	40	7
Date: 06/24/1993	ISR Number: 985110-3	Report Type: Periodic		Company Report N	umber: 930200	598001	Age: 46 YR		
Outcome	PT	Report Source	Product				inger, 40 IR	Gen	der: Female
Other	Abnormal Dreams	Foreign	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Consumer	Loestrin		PS	Roche	ORAL		246
	Emotional Disturbance Nos Hostility		Loesun		C				
Date: 06/24/1993	ISR Number: 985113-9	Report Type: Periodic	-	Company Report N	umbar: 930200	372001			···
Outcome	PT	Report Source	D. 1			2,3001	Age: 16 YR	Gen	der: Male
Other	Alanine Aminotransferase	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Increased Aspartate Aminotransferase Increased	ricaiui Professional	Accutane		PS	Roche	ORAL		
	Hostility								
Date: 06/24/1993 Outcome	ISR Number: 985119-X	Report Type: Periodic		Company Report No	mber: 930200	673001	Age: 31 YR	Gen	der: Female
Other	PT	Report Source	Product		Role	Manufacturer	- TD 4		2 2/11/10
	Major Depressive Disorder Nos Nail Disorder Nos	Health Professional	Accutane		PS Rote	Roche	Route ORAL	Dose/Unit	Duration .
Date: 06/24/1993	ISR Number: 985166-8	Report Type: Periodic		Company D 434					204
Outcome	PT			Company Report Nu	mber: 9202014	116001	Age: 46 YR	Gen	der: Female
Other	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Accutane		PS	Roche	ORAL		130
Date: 06/24/1993	ISR Number: 985168-1	Report Type: Periodic		Company Report Nu	mher: 920201	277001			
Outcome	_ PT	Report Source	n .	post report Nu	mu cr: 3202012	c//UU1	Age: 21 YR	Gene	der: Male
Other	Depression Nec	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos	1 To Continui	Accutane		PS	Roche	ORAL	. —	3
ate: 06/24/1993	ISR Number: 985178-4	Report Type: Periodic		Company Report Nu	mber: 9202012	180001	Age:	Gene	·
Outcome	PT	Report Source	Product					Gene	der: Female
Other	Dysphonia	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
					LP	Roche	ORAL		7

			1500000000	li internati		etem (AERS) ERonori			
Date: 06/24/1993	ISR Number: 985197-8	Report Type: Periodic		Company Report N					
Outcome	PT	Report Source		Tang and part 1	-Hiller. 92020)	1408001	Age: 35 YR	Ge	nder: Female
Other	Asthenia	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Speech Disorder Nec	Andrea Professional	Accutane		PS	Roche	ORAL		33
	Thinking Abnormal Nec								
Date: 06/24/1993	ISR Number: 985206-6	Report Type: Periodic		Company Report N	mber: 920201	1298001	Ann 2CVD		
Outcome	PT	Report Source	Product			1230001	Age: 36 YR	Ger	nder: Female
Other	Drug Interaction Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos	·	Ativan		PS	Roche	ORAL		22
Date: 06/24/1993	Urinary Retention		Autan		. C				
	ISR Number: 985901-9	Report Type: Periodic		Company Report No	mber: 920201	1609001	Age: 42 YR		
Outcome	PT	Report Source	Product	- • •			Age: 42 IK	Ger	nder: Female
	Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Skin Disorder Nos		Carisoprodol		PS	Roche	ORAL	40	175
	•		Triamcinolon		c				
			Trichloroacet		c c	-			1
			Naprosyn		. c				
Date: 06/24/1993	ISR Number: 985917-2	Report Type: Periodic		a -					
Outcome	PT			Company Report Nu	mber: 920213	87001	Age: 23 YR	Ger	ıder: Female .
Other	Alopecia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Health Professional	Accutane		PS	Roche	ORAL		105
	Headache Nos								103
	Leucopenia Nos								
ate: 07/01/1993	ISR Number: 1342518-4	Report Type: Expedited (15-Day)	Company Report Nu		07000			
Outcome	_ PT	Report Source		Company Report 140	nber; 9302010	072001	Age: 35 YR	Gen	der: Female
Disability	Agitation	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Amblyopia Nos	reath rolessional	Accutane		PS	Roche	ORAL		38
	Dry Skin Migraine Nos								
ate: 06/24/1993									
ite: 00/24/1993	ISR Number: 1344076-7	Report Type: Periodic		Company Report Nu	uber: 9202012	291001	Acc. COND		
utcome	PT	Report Source	Product				Age: 68 YR	Gen	der: Female
ther	Anxiety Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Condition Aggravated Depression Nec		Accurane		PS	Roche	ORAL		8
					. C				

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Date: 07/23/1993	ISR Number: 1346156-9								
Outcome	PT	Report Type: Expedited	(15-Day)	Company Report Nun	ber: 930201	135001	Age: 19 YR	Gene	der: Male
Hospitalization -	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Genitourinary Tract Neoplasm Nos	Health Professional	Accutane		PS	Roche	ORAL	-	120
Date: 07/27/1993	ISR Number: 1346441-0	Report Type: Expedited	(15-Day)	Company Report Num	ber: 930200	707001	Age: 24 YR		
Outcome	PT	Report Source	Product				Age. 24 IK	Gene	der: Female
Disability	Arthralgia	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Depression Nec Face Oederna Skin Atrophy		Accutane		PS	Roche	ORAL	60	123
Date: 07/21/1993	ISR Number: 1347425-9	D							
Outcome	PT	Report Type: Expedited	(15-Day)	Company Report Num	ber: 930200	952001	Age: 30 YR	Gene	der: Female
Hospitalization -	Anxiety Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Major Depressive Disorder Nos	Study	Accutane		PS	Roche	ORAL	Dustrellin	104
	Neurosis Nos Pruritus	Health Professional	Dapsone		С		314.25		
ate: 08/20/1993	ISR Number: 1353597-2	Report Type: Expedited	(15-Day)	C					·
Outcome	PT		-	Company Report Num	ber: 930201	351001	Age: 37 YR	Gene	ler: Male
Iospitalization -	Hallucination Nos	Report Source	Product	-	Role	Manufacturer	Route	Dose/Unit	Duration '
nitial or Prolonged Other	Psychotic Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL		45
	Schizophrenia Nos								
ate: 10/18/1993	ISR Number: 1377555-7	Report Type: Expedited (15-Day)	Company Report Num	020001				
utcome	PT		•	hand vehort Mum	ser: 9302010	DOSUUI	Age: 30 YR	Gend	ler: Female
isability	Depression Nec	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Headache Nos	a south i rulessional	Accutane		PS	Roche	ORAL		100
	Urinary Tract Infection Nos Weight Decreased								
te: 12/01/1993	ISR Number: 1392680-2	Report Type: Expedited (15-Day)	Communication of the communica			· · · · · · · · · · · · · · · · · · ·		
ntcome	PT		L. Day)	Company Report Numb	er: 9302020	072001	Age: 17 YR	Gend	ler: Male
ospitalization -	Cheilitis	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
tial or Prolonged	Depression Nec	Consumer	Accutane		PS	Roche	ORAL		119
her	Emotional Disturbance Nos								117
	Suicide Attempt								

		F	resident	: Event Reportin Of Information (70	Report			
Date: 02/18/1994	ISR Number: 1415650-4	Report Type: Periodic		Company Report Number: 920200509001		Age: 18 YR Gend			
Outcome	PT	Report Source	Product				16th 161K	Gen	nder: Female
Other	Cheilitis	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Conjunctivitis Nec Depression Nec		Accutane		PS	Roche	ORAL		230
D. COMENS	Personality Disorder Nos								
Date: 02/15/1994	ISR Number: 1423876-9	Report Type: Expedited (15-Day)		Company Report Number: 940200275001			Age: 14 YR	Ger	nder: Male
Ontcome	PT	Report Source	Product	,	Role	Manufacturer	n		_
Death	Suicide Attempt	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
Date: 03/14/1994	TCD No. 1 1407470 -			· · · · · · · · · · · · · · · · · · ·		140410	URAL	40	85
	ISR Number: 1427679-0	Report Type: Expedited (15-Day)		Company Report Number: 940200369001			Age:	Ger	nder: Female
Outcome	<u>PT</u>	Report Source	Product	. 1	Role	Manufacturer	Route	D#1-**	
Disability	Amnesia Nec Benign Intracranial Hypertension	Health Professional	Accutane		PS .	Roche	Kottle	Dose/Unit	Duration
	Personality Disorder Nos								
Date: 03/14/1994	ISR Number: 1428577-9	Report Type: Expedited (15-Day)		Company Report Number: 940200372001			Age: 14 YR	Ger	nder: Male
Outcome	PT PT	Report Source	Product	1	Role	Manufacturer	Route	D 67 11	
Death	Dry Skin Suicide Attempt	Health Professional	Accutane		's	Roche		Dose/Unit	Duration
Life-Threatening	Suicide Attempt		Bactrim Ds			Kone	ORAL	80	61
		Report Type: Expedited (15-Day)		Company Report Number: 940804020001			·		
Date: 03/29/1994	ISR Number: 1435876-3	Report Type: Expedited (15-Day)	Company Report Number:	9408040	120001	Age: 28 YR	Gen	der Paul
	ISR Number: 1435876-3						Age: 28 YR	Gen	ıder: Female
Outcome Hospitalization -	PT Aphasia	Report Source	Product	<u>B</u>	Role	Manufacturer	Age: 28 YR Route	Gen Dose/Unit	nder: Female
Outcome Hospitalization - Initial or Prolonged	PT			<u>B</u>			- ,		
Outcome Hospitalization - Initial or Prolonged Outcome	PT Aphasia Cerebrovascular Accident Nos Headache Nos ISR Number: 1453476-6	Report Source Foreign	Product Accutane	<u>B</u>	kole_ PS	Manufacturer Roche	Route	Dose/Unit	Duration
Outcome Hospitalization - Initial or Prolonged Date: 03/30/1994 Outcome	PT Aphasia Cerebrovascular Accident Nos Headache Nos ISR Number: 1453476-6 PT	Report Source Foreign Health Professional	Product Accutane	P Company Report Number: 9	Role PS 9402004	Manufacturer Roche	Route ORAL Age: 15 YR	Dose/Unit 40	Duration 21 ader: Male
Outcome Hospitalization - Initial or Prolonged Date: 03/30/1994 Outcome Hospitalization -	PT Aphasia Cerebrovascular Accident Nos Headache Nos ISR Number: 1453476-6 PT Agitation	Report Source Foreign Health Professional Report Type: Expedited (Product Accutane 15-Day)	P Company Report Number: 9	Role_ PS 9402004 Role	Manufacturer Roche 453001 Manufacturer	Route ORAL Age: 15 YR Route	Dose/Unit	Duration 21
Outcome Hospitalization - Initial or Prolonged Date: 03/30/1994 Outcome Hospitalization - Initial or Prolonged	PT Aphasia Cerebrovascular Accident Nos Headache Nos ISR Number: 1453476-6 PT Agitation Hostility	Report Source Foreign Health Professional Report Type: Expedited (Report Source Health Professional	Product Accutane 15-Day) Product Accutane	P Company Report Number: S	Role_ PS 9402004 Role	Manufacturer Roche	Route ORAL Age: 15 YR	Dose/Unit 40	Duration 21 ader: Male
Outcome Hospitalization - initial or Prolonged Pate: 03/30/1994 Outcome Hospitalization - initial or Prolonged ate: 05/31/1994	PT Aphasia Cerebrovascular Accident Nos Headache Nos ISR Number: 1453476-6 PT Agitation Hostility ISR Number: 1458316-7	Report Source Foreign Health Professional Report Type: Expedited (Report Source	Product Accutane 15-Day) Product Accutane	P Company Report Number: S	9402004	Manufacturer Roche 453001 Manufacturer Roche	Route ORAL Age: 15 YR Route	Dose/Unit 40 Gen Dose/Unit	Duration 21 ader: Male
Outcome Hospitalization - initial or Prolonged Pate: 03/30/1994 Outcome Hospitalization - initial or Prolonged ate: 05/31/1994 Outcome	PT Aphasia Cerebrovascular Accident Nos Headache Nos ISR Number: 1453476-6 PT Agitation Hostility ISR Number: 1458316-7 PT	Report Source Foreign Health Professional Report Type: Expedited (Report Source Health Professional	Product Accutane 15-Day) Product Accutane	Company Report Number: S	9402004 Role S	Manufacturer Roche 453001 Manufacturer Roche	Route ORAL Age: 15 YR Route ORAL Age:	Dose/Unit 40 Gen Dose/Unit	Duration 21 Inder: Male Duration
Outcome Hospitalization - Initial or Prolonged Date: 03/30/1994 Outcome Hospitalization -	PT Aphasia Cerebrovascular Accident Nos Headache Nos ISR Number: 1453476-6 PT Agitation Hostility ISR Number: 1458316-7	Report Source Foreign Health Professional Report Type: Expedited (Report Source Health Professional Report Type: Expedited (Product Accutane 15-Day) Product Accutane 15-Day)	Company Report Number: S	9402004 Role S 9404002	Manufacturer Roche 453001 Manufacturer Roche	Route ORAL Age: 15 YR Route ORAL	Dose/Unit 40 Gen Dose/Unit	Duration 21 der: Male Duration

		T.	recion (Event Reports If Information		Report			
Date: 05/18/1994	ISR Number: 1460002-4	Report Type: Direct		Company Report Numb	er:		Age: 42 YR	Gene	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	D		
Disability	Amnesia Nec	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
	Arthralgia Ecchymosis		Voltaren		C	Rocite	ORAL	80	24
	Hyperlipidaemia Nos		Tylenol		c				
Date: 05/23/1994	ISR Number: 1463654-8	Report Type: Periodic		Company Report Numb		(01001			
Outcome	PT			Company Report Millip	er: 930201	621001	Age: 28 YR	Gene	der: Female
•	Alopecia	Report Source Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Consumer	Accutane		PS	Roche	ORAL		76
	Headache Nos								
Date: 05/23/1994	ISR Number: 1463671-8	Report Type: Periodic	Company Report Number: 930201598001				Age: 27 YR	Gene	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	D 67. 14	.
	Dry Eye Nec Emotional Disturbance Nos Hostility	Consumer	Accutane		PS	Roche	ORAL	Dose/Unit	Duration 51
Date: 05/23/1994 Outcome	ISR Number: 1463674-3	Report Type: Periodic		Company Report Number	er: 930201	601001	Age: 16 YR	Gene	der: Female
	Hallucination Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Insomnia Nec	Consumer	Accutane		PS	Roche	ORAL		42
	Major Depressive Disorder Nos Personality Disorder Nos		Triphasil		С				
Date: 05/23/1994	ISR Number: 1463677-9	Report Type: Periodic		Company Report Number	r: 930201	608001	Age: 24 YR	Geno	ler: Female
Outcome	PT	Report Source	Product						renate
	Ambiyopia Nos	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Ortho-Novuz	n	PS C	Roche	ORAL		31
	Emotional Disturbance Nos Headache Nos								
Date: 05/23/1994 Outcome	ISR Number: 1463709-8	Report Type: Periodic		Company Report Number: 930201580001			Age: 19 YR	Gend	ler: Female
	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D
	Abdominal Pain Nos Depression Nec	Health Professional	Accutane		PS	Roche	ORAL	DOSE CHIL	Duration
	Migraine Nos						OKAL		6
	Vaginitis								