		100								2573000000000000000000000000000000000000
				e Event Report Of Information						
						rakipinis.				
Date: 06/24/1993	ISR Number: 980830-9	Report Type: Periodic	Product	Company Report Numb	Ann Model CO.	060 <b>bb</b> tmafastus	D4-			
Outcome	PT		Accutane	Company Report Name	PS	Roche	Route ORAL	Dose/Unit	Duration	
Other	Dizziness (Exc Vertigo)					10000	OKAL		31	
	Headache Nos Lymphadenopathy									
	Neurosis Nos									
Date: 06/24/1993	ISR Number: 980836-X	Report Type: Periodic		Company Report Numb	930200	210001				
Outcome	PT	Report Source	D			219001	Age: 24 YR	Ger	ider: Male	
Other	Emotional Disturbance Nos	Health Professional	Product Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
	Hostility		Accutante		PS	Roche	ORAL		123	
Date: 06/24/1993	Hyperkinetic Syndrome									
	ISR Number: 980838-3	Report Type: Periodic		Company Report Number	er: 930200	222001	Age: 17 YR	Gen	ider: Male	
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer	Route			
Other	Depression Nec	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration 21	
Date: 06/24/1993	ISR Number: 980851-6	Report Type: Periodic				· ·	- OKAL		Z1	
Outcome	PT			Company Report Number	ar: 920200	727001	Age: 27 YR	Gen	der: Female	
Other	Depression Nec	Report Source Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
		Consumer	Accutane		PS	Roche	ORAL		366	
Date: 06/24/1993	ISR Number: 980861-9	Report Type: Periodic		Company Report Numbe	r: 9202010	033001	Ann go sen			
Outcome	PT	Report Source	Product			erik in esa era.	Age: 22 YR	Gen	der: Male	
Other	Acne Nos	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration	
	Bone Disorder Nos Libido Decreased					Roche	ORAL		164	
	Pallor									
Date: 06/24/1993	ISR Number: 980864-4	Report Type: Periodic		Company Report Numbe	r: 9202010	739001	A 00			
Outcome	<u>PT</u>	Report Source	Product				Age: 22 YR	Gen	der: Female	
Other	Appetite Increased	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
	Condition Aggravated Hypoglycaemia Nos		Glucose, D-		PS C	Roche	ORAL		67	
	Nervousness		*		-					
Date: 06/24/1993	ISR Number: 980867-X	Report Type: Periodic		Company D						
Outcome	PT			Company Report Number	r: 9202010	41001	Age: 16 YR	Gen	der: Male	
Other	Dermatitis Nos	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit_	Duration	
<del></del>	Dry Mouth		Accutane		PS	Roche	ORAL	,		
08/03/200	0									
							1	Page 85	of 487	

		1	Teedon	Esont Reporti Or Internation		Report			
Date: 05/23/1994 Outcome	ISR Number: 1463899-7	Report Type: Periodic		Company Report Number	r: 930201	632001	Age: 42 YR	Ge	nder: Male
	Anxiety Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Headache Nos Rash Maculo-Papular Vision Abnormal Nec	Health Professional	Accutane		PS	Roche	ORAL	40	91
Date: 05/23/1994	ISR Number: 1463936-X	Report Type: Periodic	r	Company Report Number	r: 930201	646001	Age: 16 YR	Ge	nder: Male
Outcome	PT	Report Source	Product		D-1.	34	2 .		
	Palpitations	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
T	<del></del>		, recurant		PS	Roche	ORAL	80	39
Date: 05/23/1994 Outcome	ISR Number: 1464124-3	Report Type: Periodic		Company Report Numbe	r: 930202	088001	Age: 24 YR	Ge	nder: Female
vine	Dyspareunia Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Infection Nos	Consumer	Accutane		PS	Roche		80	*- 41 anon
	Ovarian Disorder Nos		Tri-Norinyl		С			60	
	Vaginal Discharge		Tylenol		c				
Date: 05/23/1994	ISR Number: 1464134-6	Report Type: Periodic		Company Report Numbe	r: 930200	772001	Age: 38 YR	Ger	nder: Female
Outcome	_ <u>PT</u>	Report Source	Product		Role	Manufacturer		_	
	Abnormal Dreams	Health Professional	Accutane		PS		Route	Dose/Unit	Duration
Date: 05/23/1994	ISR Number: 1464189-9	Report Type: Periodic	<del></del>	Company Report Number		Roche	ORAL	40	165
Outcome	PT			Company Report Number	940200	127001	Age: 17 YR	Ger	nder: Male
	Chest Pain	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Palpitations Tachycardia Nos	Health Professional	Accutane		PS	Roche	ORAL	60	88
Date: 05/23/1994	ISR Number: 1464193-0	Report Type: Periodic		Company Report Number	9302020	92001	Age:	Cer	ıder: Female
Outcome	PT	Report Source	Product				•		range
	Amnesia Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Dizziness (Exc Vertigo) Headache Nos		. Iconano		PS	Roche			1
Date: 05/23/1994	ISR Number: 1464209-1	Report Type: Periodic		Company Report Number	: 9302008	16001	Age: 17 YR	Ger	ader: Male
Outcome	PT	Report Source	Product		Dolo	Manuel	-		
	Apathy	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	High Density Lipoprotein Decreased		, recutatio		PS	Roche	ORAL	80	109 -

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						111111111			
Date: 05/23/1994	ISR Number: 1464242-X	Report Type: Periodic		Company Report N	mber: 93020	2135001	Age: 38 YR		
Outcome	PT	Report Source	Product				Age: 38 1 K	Ges	nder: Female
	Palpitations	Consumer	Accutane	<del></del>	Role	Manufacturer	Route	Dose/Unit	Duration
			Norplant		PS	Roche	ORAL	60	156
Date: 05/23/1994	ISR Number: 1464245-5	Report Type: Periodic	1 (captain	<del></del>	C	· · · · · · · · · · · · · · · · · · ·	<del></del>	<del></del>	
Outcome	Ton	report Type, remone		Company Report No	mber: 930202	2136001	Age: 20 YR	Ger	nder: Female
Outcome	Dry Eye Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos	Consumer	Accutane		PS	Roche	ORAL	Dose Cint	Duration
	Urinary Incontinence								
	Vomiting Nos								
Date: 05/23/1994	ISR Number: 1465441-3	Report Type: Periodic		Company Report Nu		500001	· · · · · · · · · · · · · · · · · · ·		
Outcome	PT	Demost C	1	company Report No	unoer: 940200	200001	Age: 30 YR	Ger	nder: Male
	Impotence	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		ricalui riotessional	Accutane		PS	Roche	ORAL	40	141
Date: 05/23/1994	ISR Number: 1465510-8	Report Type: Periodic		Company Report Nu	- h - 040000	170001			<del></del>
Outcome	PT			Company Report Nu	mber: 940200	473001	Age: 17 YR	Gen	ider: Male
	Acne Nos	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Asthenia	ricaim Professional	Accutane		PS	Roche	ORAL	80	2656
	Depression Nec								
	Eczema Nos								
Date: 05/23/1994	ISR Number: 1465520-0	Report Type: Periodic		Company Report Nu	mher- 940200	423001		<del> </del>	
Outcome	PT	Report Source				T2JUUI	Age: 16 YR	Gen	ider: Male
	Cheilitis	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Insomnia Nec		Accutane		PS .	Roche	ORAL	80	109
Date: 05/23/1994	ISR Number: 1465529-7	Report Type: Periodic		Communication					
Outcome	PT	· · · · · · · · · · · · · · · · · · ·		Company Report Nu	nber: 940200	\$52001	Age:	Gen	der: Unknown
	Hallucination Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Accutane	•	PS	Roche	ORAL		
Date: 05/23/1994	ISR Number: 1465564-9	Report Type: Periodic		C				<del></del>	
Outcome	PT			Company Report Nur	nber: 9402002	263001	Age: 27 YR	Gen	der: Male
	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	•	Consumer	Accutane		PS	Roche	ORAL	80	169

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Date: 05/23/1994	ISR Number: 1465572-8	Report Type: Periodic		Company Report	Number: 940200	276001	Age: 17 YR	C=	ider: Male	
Outcome	PT	Report Source	Product					· Ga	ider: Male	
	Chest Pain	Health Professional	Accutane	<del></del>	Role	Manufacturer	Route	Dose/Unit	Duration	
	Hypoaesthesia		Ac-Allergen	- D	PS	Roche	ORAL		60	
	Palpitations		At-Allergen	c Extracts	С					
Date: 05/23/1994	ISR Number: 1465582-0	Report Type: Periodic		Company Report	Name 140200	14004				
Outcome	PT			Company Report	Munimer: 940200.	348001	Age: 27 YR	Ger	ider: Female	
	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Emotional Disturbance Nos	Consumer	Accutane		PŚ	Roche	ORAL		32	
	Hostility								32	
Date: 05/23/1994	ISR Number: 1465618-7									
		Report Type: Periodic		Company Report	Number: 9402004	160001	Age: 37 YR	Ger	ıder: Female	
Outcome	PT	Report Source	Product		Role	35	· _			
	Depression Nec	Consumer	Accutane		PS Role	Manufacturer	Route	Dose/Unit	Duration	
	Headache Nos Skin Discolouration				rs	Roche	ORAL	60	21	
	Vision Abnormal Nec							•		
Date: 05/23/1994			· · · · · ·							
	ISR Number: 1465704-1	Report Type: Periodic		Company Report	wmber: 9402006	83001	Age: 28 YR			
Outcome	PT	Report Source	Product				Age. 20 IK	Gen	der: Female	
	Alopecia	Consumer			Role	Manufacturer	Route	Dose/Unit	Duration	
	Depression Nec	· ·	Accutane		PS	Roche	ORAL.		130	•
	Drug Ineffective		Erythromycin		С					
<del></del>	Myalgia									
Date: 05/23/1994	ISR Number: 1465742-9	Report Type: Periodic		Company D			<del></del>			
Outcome	PT			Company Report !	umber: 9402003	14001	Age: 18 YR	Gen	der: Female	
	Hypercholesterolaemia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Palpitations	Health Professional	Accutane		PS	Roche	ORAL	40	45	
	Tachycardia Nos		Triphasil		. С				73	
Date: 05/23/1994	ISR Number: 1465752-1	Day 4 May 20 1				<del>-, ·</del>				
		Report Type: Periodic		Company Report P	umber: 9402003	58001	Age:	Gen	der: Female	
Outcome	PT	Report Source	Product		Role	Manufacture	<b>.</b> .			
	Acne Nos	Consumer	Accutane		PS Role	Manufacturer	Route	Dose/Unit	Duration	
	Bone Pain Depression Nec				rs	Roche	ORAL		77	
	Dry Skin									

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			180,000	Of information (Ff)	D Report		
Date: 05/23/1994	ISR Number: 1465766-1	Report Type: Periodic		Company Report Number: 9402	00372002	Age: 14 YR	
Outcome	PT	Report Source	Product			. 14 I K	Gender: Male
	Depression Nec	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit Duration
Date: 05/23/1994	Top N. A. Alexandre		Accorate	PS	Roche	ORAL	80 166
	ISR Number: 1465786-7	Report Type: Periodic		Company Report Number: 9302	01321001	Age: 43 YR	Gender: Male
Outcome	PT	Report Source	Product	Role	Manufacturer	D4-	
	Anxiety Nec Depression Nec	Health Professional	Accutane	PS	Roche	Route ORAL	Dose/Unit Duration 22
Date: 05/23/1994	ISR Number: 1465849-6	Report Type: Periodic		Company Broad N. A. Green			
Outcome	PT	Report Source		Company Report Number: 9402	00087001	Age: 23 YR	Gender: Male
	Impotence	Health Professional	Product	Role	Manufacturer	Route	Dose/Unit Duration
		Treatm Liorestolial	Accutane	PS	Roche	ORAL	125
Date: 05/23/1994	ISR Number: 1465852-6	Report Type: Periodic		Company Report Number: 9402	00701001	Age: 52 YR	Gender: Female
Outcome	PT PT	Report Source	Product	Role	Manufacturer	n	
	Depression Nec	Consumer	Accutane	PS	Roche	Route	Dose/Unit Duration
			Maxzide	C	ROLLE	ORAL,	* .
	· · · · · · · · · · · · · · · · · · ·		Tenormin	c			
Date: 05/23/1994	ISR Number: 1465926-X	Report Type: Periodic		Company Report Number: 94020	00733001	Age: 36 YR	
Outcome	PT	Report Source	Product			Age: 30 1K	Gender: Female
	Depression Nec Emotional Disturbance Nos	Health Professional	Accutane	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit Duration
Date: 05/23/1994	ISR Number: 1465928-3	Report Type: Periodic		C			56
Outcome	PT			Company Report Number: 94020	XV738001	Age: 26 YR	Gender: Female
	Depression Nec	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Duration
	Headache Nos	Health Professional	Accutane	PS	Roche	ORAL	50 1
Date: 05/23/1994	ISR Number: 1465931-3	Report Type: Periodic		Company Report Number: 94020	0741001	Age: 18 YR	Gender: Female
Outcome	PT	Report Source	Product			_	Gender: Female
	Emotional Disturbance Nos	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit Duration
			·	PS PS	Roche	ORAL	152
Nafe: 05/23/1004	TOTAL A CASE OF THE PARTY OF TH						
	ISR Number: 1465943-X	Report Type: Periodic		Company Report Number: 94020	0705001	Age: 17 YR	Gender: Male
Outcome	ISR Number: 1465943-X PT Dysphonia	Report Type: Periodic	Product	Company Report Number: 94020	0705001 Manufacturer	Age: 17 YR	Gender: Male  Dose/Unit Duration

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ate: 05/23/1994	ISR Number: 1465995-7	Report Type: Periodic		Company Report Number			Age: 34 YR		ider: Female
Outcome	PT	Report Source	Product					Ga	ider: Female
	Ataxia Nec	Consumer			Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos Hostility		Accutane		PS	Roche	ORAL	80	121
_	Photosensitivity Reaction Nos								
nte: 05/23/1994 Outcome	ISR Number: 1466005-8	Report Type: Periodic		Company Report Number	r: 940200	473002	Age: 17 YR	Gen	nder: Female
Jacone	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos	Health Professional	Accutane		PS	Roche	ORAL	Dude Chit	42
	Myalgia Vision Abnormal Nec		Onho-Novum		С		OKAL		42
ate: 05/23/1994	ISR Number: 1466015-0	Report Type: Periodic		Company Report Numbe	r: 940200:	210001	Age: 16 YR	Gen	der: Male
utcome	PT	Report Source	Product				-		mer: Mate
	Agitation	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Hallucination Nos		Cipro		PS	Roche	ORAL		90
	Hostility Hyperkinetic Syndrome		Сарао		С				
ite: 05/23/1994	ISR Number: 1466062-9		<del></del>						
		Report Type: Periodic		Company Report Number	9402003	376001	Age: 18 YR	Gen	der: Male ·
Outcome	Pr	Report Source	Product		D.1.	34 4 .			Maic
	Depression Nec	Health Professional	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration
	Hostility Personality Disorder Nos				PS	Roche	ORAL	80	28
	Thinking Abnormal Nec								
ite: 05/23/1994	ISR Number: 1466080-0	Report Type: Periodic		Company Report Number	9402003	28001	Age: 37 YR	Gen	· ·
utcome	PT	Report Source	Product						der: Female
	Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Varicose Veins Nos Vascular Disorder Nos		· white		PS	Roche			93
te: 05/23/1994	ISR Number: 1466083-6	Report Type: Periodic		Company Report Number	9402003	26001	Age: 48 YR		
ntcome	PT	Report Source	Product			<del>-</del>	12ge: 40 IK	Gene	der: Female
	Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Dry Skin				PS	Roche	ORAL	80	3
	Eye Pain		Estraderm		С				

### FDA - Adverse Event Reporting Sectem (A Etsedom Of Information (ECD Repo Date: 05/23/1994 ISR Number: 1466124-6 Report Type: Periodic Company Report Number: 940200241001 Age: 17 YR Gender: Male Outcome Report Source Product Role Manufacturer Depression Nec Dose/Unit Duration Health Professional Accutane Emotional Disturbance Nos PS Roche ORAL 40 Date: 05/23/1994 ISR Number: 1469077-X Report Type: Periodic Company Report Number: 930201176001 Age: 14 YR Gender: Male Report Source Product Role Emotional Disturbance Nos Manufacturer Dose/Unit Duration Health Professional Accutane PS Roche ORAL Desquam-X С Date: 05/23/1994 ISR Number: 1469105-1 Report Type: Periodic Company Report Number: 930201175001 Age: 21 YR Gender: Female Outcome Report Source Product Disability Role Manufacturer Route Dose/Unit Duration Depression Nec Health Professional Accutane PS ORAL 24 Date: 05/23/1994 ISR Number: 1469107-5 Report Type: Periodic Company Report Number: 930201093001 Age: 30 YR Gender: Female Outcome Report Source Product Role Hospitalization -Abdominal Pain Nos Route Dose/Unit Duration Health Professional Initial or Prolonged Alopecia Roche ORAL 1948 Conjunctivitis Nec Nervousness Date: 05/23/1994 ISR Number: 1469109-9 Report Type: Periodic Company Report Number: 930200923001 Age: 34 YR Gender: Female Outcome Report Source Product Role Manufacturer Hospitalization -Depression Nec Route Dose/Unit Duration Health Professional Initial or Prolonged Accutane PS Roche ORAL, Lithium C Date: 05/23/1994 ISR Number: 1469165-8 Report Type: Periodic Company Report Number: 930201160001 Age: 18 YR Gender: Male Report Source Role Manufacturer Depression Nec Route Dose/Unit Duration Health Professional Accutane PS ORAL 215 Date: 05/23/1994 ISR Number: 1469373-6 Report Type: Periodic Company Report Number: 930201255001 Age: 18 YR Gender: Male Outcome Report Source Product Role Manufacturer Depression Nec Route Dose/Unit Duration Health Professional Accutane Dry Skin PS ' Roche ORAL 160 Dyspnoea Nos

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Date: 05/23/1994	ISR Number: 1469476-6	Report Type: Periodic		Company Report Numb						
Outcome	PT	Report Source	D 1				Age: 23 YR	Ge	nder: Female	
	Asthenia	Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Depression Nec Nausea Weight Decreased		Accutane		PS	Roche	ORAL	160	187	
Date: 05/23/1994						1.	•			ı
Outcome	ISR Number: 1469489-4 PT	Report Type: Periodic		Company Report Numb	er: 930200	865001	Age:	Ge	nder: Female	$\dashv$
	Depression Nec	Report Source	Product		Role	Manufacturer	Route	D		
	Drug Interaction Nos	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration	
	Drug Level Nos Below Therapeutic		Amitriptylin	e	SS		ORAL		120 120	
Date: 05/23/1994	ISR Number: 1469491-2	Report Type: Periodic		Company Report Number	er: 930200	864001	4			_
Outcome	PT	Report Source	Dundand		21 200200	004001	Age:	Gea	ıder: Male	
<u> </u>	Palpitations	Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration	
Date: 05/23/1994	ISR Number: 1469497-3	Report Type: Periodic		Company			ORAL			
Outcome	<u>PT</u>	Report Source	Product	Company Report Number			Age: 17 YR	Gen	der: Female	
	Depression Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
Date: 05/23/1994	Personality Disorder Nos		recolane		PS	Roche	ORAL		59	
	ISR Number: 1469509-7	Report Type: Periodic		Company Report Numbe	- 030201	(18001			<del></del>	_
Outcome	PT	Report Source	D	Tany assport runne	1. 930201	18001	Age: 17 YR	Gen	der: Male	
Disability	Acne Nos	Health Professional	Product	·	Role	Manufacturer	Route	Dose/Unit	Duration	
	Condition Aggravated	I to continu	Accutane		PS	Roche	ORAL	80	20	ŀ
	Insomnia Nec Pain Nos								20	
ate: 05/23/1994	<del></del>									İ
Aute. 03/23/1994	ISR Number: 1469513-9	Report Type: Periodic		Company Report Number	0202020					
Outcome	PT	Report Source			9302022	29001	Age: 26 YR	Gen	der: Female	
Iospitalization -	Depression Nec	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration	1
nitial or Prolonged ate: 05/23/1994	Emotional Disturbance Nos	- Andrew Froressional	Accutane		PS	Roche	ORAL		46	
	ISR Number: 1469524-3	Report Type: Periodic		Company Report Number	9402003	26002	A 103m			_
utcome	PT	Report Source	Product	-			Age: 19 YR	Gene	ler: Female	
Disability	Cheilitis	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
	Conversion Disorder		Accutance		PS	Roche	ORAL			1

## Ececión Of Information (FOL) Date: 05/23/1994 ISR Number: 1469545-0 Report Type: Periodic Company Report Number: 940200495001 Age: Gender: Female Outcome Report Source Product Life-Threatening Cheilitis Role Dose/Unit Duration Health Professional Accutane PS Depression Nec Roche ORAL Hospitalization -97 Emotional Disturbance Nos Initial or Prolonged Suicide Attempt Date: 05/23/1994 ISR Number: 1469623-6 Report Type: Periodic Company Report Number: 930201224001 Age: 25 YR Gender: Female Outcome Report Source Product Cheilitis Route Dose/Unit Duration Health Professional Depression Nec PS Roche ORAL 154 Gingival Bleeding Headache Nos Date: 05/23/1994 ISR Number: 1469905-8 Report Type: Periodic Company Report Number: 940200063001 Age: 24 YR Gender: Female Outcome Report Source Product Role Convulsions Nos Manufacturer Route Dose/Unit Duration Health Professional Accutane Depersonalisation PS Roche ORAL 31 Headache Nos Sedation Date: 05/23/1994 ISR Number: 1469926-5 Report Type: Periodic Company Report Number: 930201683001 Age: 16 YR Gender: Female Outcome Report Source Product Condition Aggravated Role Route Health Professional Depression Nec PS Roche ORAL Desyrel Bristol Labs Emotional Disturbance Nos SS ORAL Headache Nos Date: 05/23/1994 ISR Number: 1469957-5 Report Type: Periodic Company Report Number: 930201640001 Age: 16 YR Gender: Male Outcome Report Source Product Role Manufacturer Dose/Unit Duration Asthenia Health Professional Accutane PS Depression Nec Roche ORAL Date: 05/23/1994 ISR Number: 1469980-0 Report Type: Periodic Company Report Number: 940200095001 Age: 16 YR Gender: Female Outcome PT Report Source Product Thinking Abnormal Nec Role Manufacturer Route Dose/Unit Duration Health Professional Accutane PS Roche ORAL 40 131

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Date: 05/23/1994	YOU								
	ISR Number: 1469999-X	Report Type: Periodic		Company Report Numb	er: 94020	0084001	Age: 15 YR	Ge	nder: Male
Outcome	PT	Report Source	Product		Role	Manufacturer			
	Depression Nec	Health Professional	Accutane		PS	Roche	Route ORAL	Dose/Unit 20	Duration 31
Date: 05/23/1994	ISR Number: 1470068-3	Report Type: Periodic		Company Report Numb	93020	712001	·		
Outcome	PT	Report Source	D- 1 -	, , , , , , , , , , , , , ,			Age: 15 YR	Ger	nder: Pemale
	Depression Nec	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		- Ioutil i foressional	Accutane		PS	Roche	ORAL	80	
Date: 05/23/1994	ISR Number: 1470169-X	Report Type: Periodic		Company Report Numb	er: 930201	791001	Age: 49 YR	Ge	ıder: Male
Outcome	PT	Report Source	Product		Role	Manufacturer			Iviale
	Appetite Increased Libido Decreased	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
D-4. DEPOUGO:		<del> </del>				ROUSE	ORAL,	80	
Date: 05/23/1994	ISR Number: 1470244-X	Report Type: Periodic		Company Report Numb	er: 930201	839001	Age: 29 YR	:	
Outcome	_ <u>PT</u>	Report Source	Product	-			Age. 29 I K	Ger	ider: Female
	Amnesia Nec	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
			Account		PS	Roche	ORAL	80	158
Date: 05/23/1994	ISR Number: 1470389-4	Report Type: Periodic		Company Report Number	er: 930201	914001	A		
Outcome	PT	Report Source	Product			J11001	Age: 35 YR	Ger	ider: Female
	Arthralgia	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Back Pain		Triphasil		PS	Roche	ORAL	40	
	Insomnia Nec Joint Disorder Nos		rathaan		С	are a second of the second			
D. ( 05 00 400 (	<del></del>				<i>-</i>				
Date: 05/23/1994	ISR Number: 1470398-5	Report Type: Periodic		Company Report Numbe	r: 930201	913001	Age: 43 YR		
Outcome	PT	Report Source	Product				age: 43 YK	Gen	der: Female
	Palpitations	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
			Accurate		PS	Roche	ORAL	40	15
Date: 05/23/1994	ISR Number: 1470503-0	Report Type: Periodic		Company Report Numbe	930201	888001			
Outcome	PT	Report Source	Decident	, ,pozer-tunitie	>50201	300001	Age: 35 YR	Gen	der: Female
	Alopecia	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Hyperlipidaemia Nos	- Actual 1 totostonal	Accutane		PS	Roche	ORAL	80	25
	Palpitations								
	Skin Discolouration								

			8 6 V 8 (*) * 1	Officioenada		Repart			
Date: 05/23/1994	ISR Number: 1470522-4	Report Type: Periodic		Company Report Numi	ber: 930201	549001	Age: 45 YR		nder: Female
Outcome	PT	Report Source	Product					- Gu	nder: Female
	Abnormal Dreams	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
<del></del>	Depression Nec	· <u>·</u>			PS	Roche	ORAL		
Date: 05/23/1994	ISR Number: 1470526-1	Report Type: Periodic		Company Report Numl	ham 940200	120001	· · · · · · · · · · · · · · · · · · ·		
Outcome	PT	Report Source	D		JEE . 340200	129001	Age: 32 YR	Ger	nder: Female
	Dry Skin	Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos	Consumer	Accutane		PS	Roche	ORAL	40	37
	Hostility		Vitamin B	Complex	C				
Date: 05/23/1994	ISR Number: 1470735-1	Report Type: Periodic		Company Report Numb	930201	272001			
Outcome	PT			hand webott Mille	rer: 930201.	3/3001	Age: 18 YR	Ger	nder: Male
	Depression Nec	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Thinking Abnormal Nec	rotessional	Accutane		PS	Roche	ORAL.		12
Date: 05/23/1994	ISR Number: 1470805-8	Report Type: Periodic		Common D					· · · · · · · · · · · · · · · · · · ·
Outcome	PT			Company Report Numb	er: 930201	170001	Age: 38 YR	Gen	der: Female
Hospitalization -	Agitation	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Depression Nec	Health Professional	Accutane		PS	Roche	ORAL	80	115
	Thinking Abnormal Nec		Lithium		С		3.4.4.	80	115
Date: 05/23/1994	ISR Number: 1470856-3	Report Type: Periodic		~ -	-	· · · · · · · · · · · · · · · · · · ·	·		
Outcome	PT			Company Report Numb	er: 9402000	035001	Age:	Gen	der: Male
	Depression Nec	Report Source	Product	<u> </u>	Role	Manufacturer	Route	Dose/Unit	Duration
<del></del>	•	Health Professional	Accutane		PS	Roche	_		Duration
Date: 05/23/1994	ISR Number: 1470895-2	Report Type: Periodic			10.00		<u> </u>	· · · · · · · · · · · · · · · · · · ·	
Outcome	PT			Company Report Numb	er: 9402000	080001	Age: 36 YR	Gen	der: Female
	Dyspnoea Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Hypercholesterolaemia	Health Professional	Accutane		PS	Roche	ORAL	80	130
	Hyperlipidaemia Nos								130
·	Palpitations								
Date: 05/23/1994	ISR Number: 1472107-2	Report Type: Periodic		Company Report Number					
Outcome	PT			Company Report Number	er: 9302014	90001	Age: 25 YR	Gen	der: Female
	Arthralgia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Cheilitis	Health Professional	Accutane		PS	Roche	ORAL	160	123
	Depression Nec		Norplant		С				
	Hyperlipidaemia Nos								

		FDA -	Advers Cedom	e Event Reporti Of Information		tem (AERs) Remort			
Date: 05/23/1994 Outcome	ISR Number: 1472748-2	Report Type: Periodic		Company Report Number			Age: 75 YR	Ge	nder: Male
Outcome	PT Anxiety Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Back Pain Furuncle (Exc Genital) Hypertonia	Health Professional	Accutane		PS.	Roche	ORAL	40	57
Date: 05/23/1994	ISR Number: 1472883-9	Report Type: Periodic		Company Report Numbe	930201	286001	1	<del></del>	
Outcome	PT	Report Source	Product				Age: 16 YR	Gen	der: Female
	Anxiety Nec	Health Professional	Accutane	<del></del>	Role PS	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Palpitations Rectal Bleeding				13	Roche	ORAL	80	145
Date: 05/23/1994	ISR Number: 1472962-6	Report Type: Periodic		Company Report Numbe	r: 9302013	349001	Age: 29 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	D4-		
	Abnormal Dreams Dry Skin Photosensitivity Reaction Nos Sleep Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration 61
Date: 05/23/1994	ISR Number: 1473007-4	Report Type: Periodic		Company Report Numbe	m 9302011	101001			
Outcome	PT	Report Source	Product				Age: 30 YR	Gen	der: Female
Hospitalization	Alopecia	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged Disability	Emotional Disturbance Nos Headache Nos Hepatic Function Abnormal Nos				PS	Roche	ORAL	40	75
Date: 05/23/1994	ISR Number: 1473012-8	Report Type: Periodic	<del></del>						
Outcome	РТ	7-		Company Report Number	r: 9302010	12001	Age: 19 YR	Gen	der: Male
	Dry Skin	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos Epistaxis Hostility	- I ACTEOSICIEM	Accutane		PS	Roche	ORAL	60	142
Date: 05/23/1994	ISR Number: 1473022-0	Report Type: Periodic	,	Company Report Number	9302010	22002	Age: 14 YR	Gene	lan 161
Outcome	PT	Report Source	Product					Gene	ler: Male
	Confusion	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration

		FDA		e Event Report Of Information		StrickERS)				
Date: 05/23/1994	ISR Number: 1473030-X	Report Type: Periodic		Company Report Numi						
Outcome	<u>PT</u>	Report Source		1 - V Partitud	004. 930201	140002	Age: 15 YR	Ge	nder: Male	
	Emotional Disturbance Nos	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
Date: 05/23/1994			Accutane	<u> </u>	PS	Roche	ORAL			
Date: 03/23/1994	ISR Number: 1473033-5	Report Type: Periodic		Company Report Numb	020201					
Outcome	PT	Report Source		Company Report Numi	per: 930201	148001	Age: 41 YR	Ge	nder: Male	
	Emotional Disturbance Nos	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
		ricanii Fiotessionai	Accutane		PS	Roche	ORAL.	80	Duration	
			Carafate		C			30		
Date: 05/23/1994	Ten N	<del></del>	Zantac		$\mathbf{c}$					
	ISR Number: 1473062-1	Report Type: Periodic		Company Report Numb	030300	000001				
Outcome	PT	Report Source		campany report Numb	Neir: 930200	998001	Age: 29 YR	Ge	nder: Male	
	Depression Nec	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
		Ticalul Floressional	Accutane		PS	Roche	ORAL	40	49	
Date: 05/23/1994	ISR Number: 1473112-2	Report Type: Periodic				<u> </u>		. 40	49	
Outcome	PT			Company Report Number	er: 9302010	076001	Age: 35 YR	Ges	nder: Female	
	Amnesia Nec	Report Source	Product	<del></del>	Role	Manufacturer	Route	D. #7.11		
	<del></del> :	Health Professional	Accutane		PS	Roche		Dose/Unit	Duration	
ate: 07/27/1994	ISR Number: 1483540-7	D		<del></del>			ORAL	60	156	
Outcome	PT	Report Type: Expedited (1	5-Day)	Company Report Number	er: 9305011	29001	Age: 16 YR		ıder: Male	
Death	Suicide Attempt	Report Source	Product		D-1-			Ger	ıder: Malc	
ife-Threatening	Suicide Attempt	Health Professional	Rosccutane		Role	Manufacturer	Route	Dose/Unit	Duration	
					PS	Roche				
ate: 05/23/1994	ISR Number: 1484036-9	Report Type: Periodic		<del></del>						
utcome	PT			Company Report Numbe	r: 9302009	06001	Age: 42 YR		ider: Female	
	Depression Nec	Report Source	Product		Role	Manufacturer			remale	
		Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration	
			Pepcid		C	rocae	ORAL	40	64	
te: 08/09/1994	ISR Number: 1488982-1	Report Type: Expedited (15								
utcome	PT		-Day)	Company Report Number	r: 94020139	10029	Age: 24 YR	Gen	der; Female	
ospitalization -	Alopecia	Report Source	Product		Role	Manufacturer				
tial or Prolonged	Amblyopia Nos	Consumer	Accutane		PS	Roche	Route	Dose/Unit	Duration	
	Anorexia					Rocae	ORAL	80	66	
	Delusion Nos									

## Date: 07/21/1994 ISR Number: 1489427-8 Report Type: Direct Company Report Number: Age: 20 YR Gender: Male Outcome Report Source Product Manufacturer Dose/Unit Duration Other Depersonalisation Health Professional Accutane PS Thinking Abnormal Nec Minocycline SS Date: 08/17/1994 ISR Number: 1492317-8 Report Type: Expedited (15-Day) Company Report Number: 940201502001 Age: 14 YR Gender: Male Outcome Report Source Role Disability Condition Aggravated Route Dose/Unit Duration Health Professional Hostility PS Roche ORAL. 547 Personality Disorder Nos Date: 08/09/1994 ISR Number: 1495828-4 Report Type: Expedited (15-Day) Company Report Number: 940201166001 Age: 42 YR Gender: Male Outcome Report Source Role Disability Manufacturer Route Amnesia Nec Dose/Unit Duration Health Professional Accutane PS Arthralgia ORAL 24 Tylenol C Headache Nos Voltaren Myalgia С Date: 10/06/1994 ISR Number: 1507952-8 Report Type: Periodic Company Report Number: USA9304017PAM Age: Gender: Female Outcome Report Source Product Manufacturer Depression Nec Route Dose/Unit Duration Health Professional Nortriptyline Hydrochloride Drug Interaction Nos PS Sandoz ORAL Amitriptyline Drug Level Nos Below SS ORAL Therapeutic Accutane SS Roche Date: 09/14/1994 ISR Number: 1508503-4 Report Type: Expedited (15-Day) Company Report Number: 940501039001 Gender: Female Outcome Report Source Product Role Manufacturer Delirium Death Dose/Unit Duration Foreign PS Depression Nec Life-Threatening ORAL 238 Health Professional Non-Accidental Injury Suicide Attempt Date: 09/19/1994 ISR Number: 1508530-7 Report Type: Expedited (15-Day) Company Report Number: 930500702001 Age: Gender: Male Report Source Role Manufacturer Suicide Attempt Route Dose/Unit Duration Foreign Roaccutane PS Roche Life-Threatening ORAL Health Professional

							800000000000000000000000000000000000000	***************************************	200
		107		e Event Keperi	mile Ver	dem (A LRS)			
				Of Information		Report			
Date: 10/25/1994	ISR Number: 1516306-X								
		Report Type: Expedited (	(15-Day)	Company Report Numb	er: 940201	970001	Age: 16 YR	Gender:	Male
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	Dont		
Life-Threatening	Convulsions Nos Overdose Nos	Health Professional	Accutane		PS	Roche	Route ORAL	Dose/Unit Durat	ion
Hospitalization - Initial or Prolonged	Suicide Attempt		Bacitracin		С	result	OKAL	70	
	•		Benadryl		C				
			Claritin		C.				
			Sudafed		C				
Date: 11/01/1994	ISR Number: 1518823-5	Report Type: Expedited (	15-Day)	Company Report Numb	940202	D40001			
Outcome	PT	Report Source	•	- And whose Hilli	··· 710202	U+2001	Age:	Gender: ]	Male
Life-Threatening	Pain Nos	Consumer	Product		Role	Manufacturer	Route	Dose/Unit Durat	ion
Hospitalization -	Peripheral Neuropathy Nec	Schulle	Accutane		PS	Roche	ORAL		
Initial or Prolonged	Psychotic Disorder Nos		_						
Date: 11/08/1994	ISR Number: 1519340-9	Report Type: Expedited (	15-Day)	Company Report Numb	0402024	210001	<del></del>		
Outcome	PT		**	Sompany Report Pullin	er: 9402021	019001	Age: 14 YR	Gender: 1	Male
Life-Threatening	Alanine Aminotransferase	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit Durat	ion
Hospitalization -	Increased Emotional Disturbance Nos	Trouble Floressional	Accutane		PS	Roche	ORAL	60 23	
Initial or Prolonged	Suicide Attempt								
Date: 01/09/1995	ISR Number: 1539023-9	D: 45							
0.4.5		Report Type: Expedited (1	15-Day)	Company Report Number	er: 9405008	344001	Age: 20 YR	Gender:	emale
Outcome Life Theoret	PT Dermatitis Nos	Report Source	Product		Role	Manufacturer	Route		
Life-Threatening	Nervousness	Foreign	Roaccutane		PS	Roche	ORAL	Dose/Unit Durati	ion
	Suicide Attempt	Health Professional					UKAL	1	
Date: 01/31/1995	ISR Number: 1546076-0	D							
0-4		Report Type: Direct		Company Report Numbe	er:		Age: 42 YR	Gender: F	emale
Outcome	PT Alopecia	Report Source	Product		Role	Manufacturer	Route		
	Anopecia Amenorrhoea Nos	Consumer	Accutane		PS	Roche	ORAL	Dose/Unit Durati	on
	Depression Nec				-		UKAL	17	
	Hair Disorder Nos								
Date: 02/16/1995	ISR Number: 1556577-7	Report Type: Expedited (1	5 Day)			<del></del>		· · · · · · · · · · · · · · · · · · ·	
Outcome	PT		2-DHA)	Company Report Number	r: 9406001	14001	Age:	Gender: U	Inknown
Hospitalization -	Psychotic Disorder Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit Durati	on.
Initial or Prolonged		Foreign	Roscentane		PS	Roche	ORAL	Duran Duran	UR
		Health Professional					VICIL		

Date: 03/02/1995	ISR Number: 1560460-0	Report Type: Direct		Company Report Number	r:	•	Age: 21 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Agitation Emotional Disturbance Nos	Health Professional	Accutane		PS	Roche	ORAL	80	108
Required Intervention to Prevent Permanent Impairment/Damage	Personality Disorder Nos							00	108
Date: 05/23/1995	ISR Number: 1589578-3	Report Type: Expedited (	(5-Day)	Company Report Number	r: 43862	· · · · · · · · · · · · · · · · · · ·	Age: 35 YR	Gen	ıder: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Donation
Disability	Confusion Depersonalisation	Foreign	Accutane		PS	Roche	ORAL	Dose Call	Duration 35
	Drug Interaction Nos Thinking Abnormal Nec	Health Professional	Surmontil		SS	Ives Lab	ORAL		
Date: 05/05/1995	ISR Number: 1590229-2	Report Type: Direct		Company Report Number	r:	:	Age: 28 YR	Gen	der: Female
Outcome Disability	PT Amblyopia Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Other	Convulsions Nos Emotional Disturbance Nos Headache Nos	Consumer	Accutane		PS	Roche	ORAL	1	91
Date: 06/08/1995	ISR Number: 1596924-3	Report Type: Periodic		Company Report Number	r: 9402011	99001	Age: 16 YR	Gen	ıder: Male ,
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Durattan
	Asthenia Emotional Disturbance Nos	Health Professional	Accutane		PS	Roche	ORAL	40	Duration 56
Date: 06/08/1995	ISR Number: 1596931-0	Report Type: Periodic		Company Report Number	r; 9402012	44001	Age: 47 YR	Gen	der: Female
Outcome Disability	PT Asthenia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Disability	Depression Nec	Consumer	Accutane		PS	Roche	ORAL	40	31
	Headache Nos Skin Atrophy	· · · · · · · · · · · · · · · · · · ·	Thyroid		С				
	ISR Number: 1597133-4	Report Type: Periodic		Company Report Number	9402008	43001	Age: 14 YR	Gen	der: Female
Outcome	PT	Report Source	Product	<u>.                                      </u>	Role	Manufacturer	Route	Dose/Unit	Duration
	Arthralgia Depression Nec Joint Disorder Nos	Consumer	Accutane		PS	Roche	ORAL	40	93
	John Disorder Nos		<del></del>		-				

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				D. DOGGERSKIED		Septem				
Date: 06/08/1995	ISR Number: 1597135-8	Report Type: Periodic		Company Report Number	r: 940200	846001	Age: 33 YR	Gen	ider: Male	
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration	
	Asthenia Depression Nec	Consumer	Accutane		PS	Roche	ORAL	40	9	
	Headache Nos							10	,	
	Tinnitus									
Date: 06/02/1995	ISR Number: 1597164-4	Report Type: Expedited (	15-Day)	Company Report Numbe	er: 44825		Age: 17 YR		ider: Female	
Outcome	PT	Report Source	Product					Gen	ider: Female	
Disability	Dysphonia	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
<del></del>	Laryngitis Nos		Accurate		PS	Roche	ORAL			
Date: 06/08/1995	ISR Number: 1597168-1	Report Type: Periodic		Company Report Number	r: 940200	878001	Age: 25 YR	Gen	ider: Female	
Outcome	PT	Report Source	Product		Role	Manufacturer	Route			
	Agitation Dermatitis Nos	Consumer	Accutane		PS	Roche	ORAL	Dose/Unit	Duration	
	Emotional Disturbance Nos		Denmlen		C	ROLL	UKAL	20	29	
	Headache Nos				-					
Date: 06/08/1995	ISR Number: 1597184-X	Report Type: Periodic		Company Report Numbe	r: 940201	107001	Age: 15 YR		ıder: Female	
Outcome	PT	Report Source	Product					Gen	ider: Female	
	Amnesia Nec	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
	Asthenia		Monodox		PS C	Roche	ORAL		95	
Date: 06/08/1995	Headache Nos		1 1 1 1 1 1		<u> </u>	<u> . La porta de algenta de esperta</u>	e and the second			
Date: 06/08/1995	ISR Number: 1597233-9	Report Type: Periodic		Company Report Numbe	r: 940201	177001	Age: 33 YR	Gen	ıder: Female	_
Outcome	PT	Report Source	Product		Role	Manufacturer	A V			
	Cheilitis	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration	
	Depression Nec Vaginitis		Buspar		C.	A COURT	ORAL	60	24	
			Dezmlen		c					
Date: 07/06/1995	ISR Number: 1608144-4	Report Type: Expedited (1	15-Day)	Company Report Number	r: 45747		Age: 21 YR	- C-	der: Female	
Outcome	PT	Report Source	Product						der. Pemale	
Hospitalization -	Aphasia	Foreign	Roaccutane		Role PS	Manufacturer	Route	Dose/Unit	Duration	
Initial or Prolonged	Headache Nos Hypoaesthesia	Health Professional	Desogestrel		SS	Roche	ORAL	30	377	
	Hypoaesthesia Visual Field Defect Nos	•	Ethinyl Estra		SS		ORAL			

		1003	0.00	t Event Report					
			novelone	Officematic		Account			
Date: 07/19/1995									
·	ISR Number: 1614711-4	Report Type: Expedited	(15-Day)	Company Report Num	ber: 46762		Age: 23 YR	Ger	ıder: Male
Outcome	PT	Report Source	Product					- Ju	tuci. Male
Life-Threatening	Convulsions Nos	Foreign	Roaccutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Suicide Attempt	Health Professional	Roaccutane		PS	Roche	ORAL	20	180
Date: 06/17/1995	ISR Number: 1615167-8	Report Type: Direct		Company Report Num					
Outcome	PT			Company Report Num	Der:		Age: 17 YR	Ger	der: Male
	Electrocardiogram Abnormal	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Nos	Health Professional	Accutane		PS	Roche		80	62
	Hypercalcaemia Palpitations		Ery-Tab		C				02
	Ventricular Extrasystoles								
Date: 06/08/1995		<del></del>							
	ISR Number: 1616217-5	Report Type: Periodic		Company Report Numi	ber: 940201	1206001	Age: 20 YR		ıder: Male
Outcome	PT	Report Source	Product				20 IK	Ger	ider: Male
	Depersonalisation	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration
	Dizziness (Exc Vertigo)	- I O COSTOLINI	Accutane		PS	Roche	ORAL	60	1
	Headache Nos		Minocin		SS	Lederie			
Date: 06/08/1995	Thinking Abnormal Nec								
ate: 00/08/1995	ISR Number: 1616413-7	Report Type: Periodic		Company Report Numl	040201	022001			
Outcome	Pr	D		Company Report Mills	Jer: 940201	932001	Age: 16 YR	Ger	der: Female
	Emotional Disturbance Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		Consumer	Accutane		PS	Roche	ORAL	50	1
ate: 06/08/1995	ISR Number: 1616423-X	Report Type: Periodic			1 102		100		
Intcome	PT	77 y 1		Company Report Numb	er: 940202	249001	Age: 32 YR	Gen	der: Female
	Arthralgia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Consumer	Accutane		PS	Roche	ORAL	Dost Citt	
	Muscle Cramps						OKAL		30
ate: 06/08/1995	ISR Number: 1616467-8	D							
utcome		Report Type: Periodic		Company Report Numb	er: 940202	254001	Age: 41 YR	Gen	der: Male
ucome	PT	Report Source	Product		D-1-	35	-		
	Insomnia Nec Nervousness	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
4. 05/00/40=			- *************************************		PS	Roche	ORAL	160	9
te: 06/08/1995	ISR Number: 1616471-X	Report Type: Periodic		Company Percent Name	040200	350001			<del></del>
atcome	PT			Company Report Numb	er: 940202	258001	Age: 15 YR	Gen	der: Female
	Amenorrhoea Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Anorexia	Consumer	Accutane		PS	Roche	ORAL		548
	Depression Nec								J+0

Date: 06/08/1995	ISR Number: 1616476-9	Report Type: Periodic		Company Report Number	r: 9402020	83001	Age: 28 YR	Ger	ider: Female
Ontcome	PT	Report Source	Product			Manufacturer			
	Alopecia	Health Professional	Accutane		Role PS	Roche	Route	Dose/Unit	Duration
	Depression Nec Dry Skin				10	Rocile	ORAL	40	147
	Rhinitis Nos					are the			
Date: 06/08/1995	ISR Number: 1616514-3	Report Type: Periodic		Company Report Number	r: 9402022	86001	Age: 16 YR	Ger	ıder: Male
Outcome	_ PT	Report Source	Product						
	Alopecia	Health Professional	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
	Back Pain Depression Nec				10	Roche	ORAL	40	113
	Vocal Cord Paralysis								
Date: 06/08/1995	ISR Number: 1616606-9	Deport Trans. Desir "	<del></del>				<del></del>	<del></del>	
Outcome		Report Type: Periodic		Company Report Number	r: 9402013	52001	Age: 21 YR	Ge	ıder: Male
Outcome	PT Arthralgia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Asthenia	Consumer	Accutane		PS	Roche	ORAL	80	
•	Depression Nec								
<del></del>	Weight Decreased								
Date: 06/08/1995	ISR Number: 1616635-5	Report Type: Periodic		Company Report Number	: 9402013	77001	Age: 20 YR	Ge	ıder: Female ·
Outcome	PT	Report Source	Product		D-15				
	Depression Nec	Health Professional	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
			Prozac		c	Roche	ORAL	50	
Date: 06/08/1995	ISR Number: 1616639-2	Report Type: Periodic	11 24 1	Company Report Number	HI CALLES	75001	Age: 24 YR	Ger	ıder: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	D #1 #	
	Arthralgia Back Pain	Consumer	Accutane		PS	Roche	ORAL	Dose/Unit	Duration
	Dysphonia					<del></del> .	OKAL	uU	66
·	Dyspnoea Nos								
Date: 06/08/1995	ISR Number: 1616660-4	Report Type: Periodic		Company Report Number	9402013	95001	Age: 23 YR	Gen	ıder: Male
Outcome	_ PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D
	Hormone Level Nos Abnormal Impotence	Health Professional	Accutane		PS	Roche	ORAL	40	Duration 30
	uniforence.		Amoxicillin		С	<del></del> .	OKAL	-10	10
<del> </del>									10

Date: 06/08/1995	ISR Number: 1616661-6	Report Type: Periodic		Company Day of N				
Outcome	PT	Report Source	Product	Company Report Number: 950200	186001 Manufacturer	Age: 25 YR Route		ider: Female
	Anorexia Depression Nec	Consumer	Accutane	PS ·	Roche	ORAL	Dose/Unit 20	Duration 24
Date: 06/08/1995	ISR Number: 1616663-X	Report Type: Periodic		Company Report Number: 9402019	903001	Age: 24 YR	Ger	ıder: Male
Outcome	PT Amnesia Nec	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	D
	Conjunctivitis Nec	Consumer	Accutane	PS	Roche	ORAL	80 80	Duration
	Drug Interaction Nos Sleep Disorder Nos					OKAL	80	81
Date: 06/08/1995	ISR Number: 1616669-0	Report Type: Periodic		Company Report Number: 9402013	99001	Age: 17 YR	Ger	ıder: Female
Outcome	_ <u>PT</u>	Report Source	Product	Role	Manufacturer	-		
	Alopecia Blindness Night	Consumer	Accutane	PS	Roche	Route	Dose/Unit	Duration
	Depression Nec			10		ORAL		132
	Emotional Disturbance Nos	*						
Date: 06/08/1995	ISR Number: 1616684-7	Report Type: Periodic		Company Report Number: 9402014	02001	Age: 37 YR	Gen	ider: Female
Outcome	PT	Report Source	Product	Role	M			
	Amnesia Nec Asthenia	Consumer	Accutane	PS	Manufacturer Roche	Route	Dose/Unit	Duration
	Depression Nec			÷5.	Rocale	ORAL	80	
	Pruritus				Harry Charles	valeziotea (h. )		
Date: 06/08/1995	ISR Number: 1616689-6	Report Type: Periodic	-	Company Report Number: 9402014	15001	Age: 19 YR		
Outcome	PT	Report Source	Product				Gen	der: Female
	Depression Nec	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit	Duration
	Nail Disorder Nos Sweating Increased			PS	Roche	ORAL	100	31
Date: 06/08/1995	ISR Number: 1616700-2	Report Type: Periodic	<del></del>	Company Report Number: 9402023	53001	Age: 21 YR	Cen	der: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	-		
	Depression Nec Emotional Disturbance Nos	Consumer	Accutane	PS	Roche	Route	Dose/Unit	Duration
Date: 06/08/1995							_	96
	ISR Number: 1616707-5	Report Type: Periodic		Company Report Number: 94020234	19001	Age: 18 YR	Gen	der: Male
Outcome Other	PT Depression Nec	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	
Ouler	Personality Disorder Nos	Health Professional	Accutane	PS	Roche	ORAL	80	Duration 93
		_				UKAL	60	93

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			(3.000)	CK Informatio		Report			
Date: 06/08/1995	ISR Number: 1616717-8	Report Type: Periodic		Company Report Num	ıber: 950200	0216001	Age: 23 YR	Ge	nder: Female
Outcome	<u>PT</u>	Report Source	Product		* *		5	- Ou	idei. remaie
	Dermatitis Nos Emotional Disturbance Nos	Consumer	Accutane		PS Role	Manufacturer	Route	Dose/Unit	Duration
	Pruritus				rs	Roche	ORAL	40	63
Date: 06/08/1995	ISR Number: 1616726-9	Report Type: Periodic	<del></del>						
Outcome		Report Type: Penodic		Company Report Nun	ber: 940202	2370001	Age: 17 YR	Ges	nder: Female
Outcome	PT Depression Nec	Report Source	Product		Role	16	_		Tanale
	Emotional Disturbance Nos	Consumer	Accutane		PS	Manufacturer Roche	Route	Dose/Unit	Duration
	Menstrual Disorder Nos		Onho-Novu	m	SS		ORAL	80	1
Date: 06/08/1995	ISR Number: 1616733-6				33	Ortho	ORAL		56
		Report Type: Periodic		Company Report Nun	ber: 940202	409001	Age: 32 YR		ider: Female
Outcome	PT	Report Source	Product					Ger	ider: Female
	Depression Nec	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Diarrhoea Nos		Accurate		PS	Roche	ORAL	40	21
D.4	Emotional Disturbance Nos			• .					
Date: 06/08/1995	ISR Number: 1616761-0	Report Type: Periodic		Company Report Num	050000				
Outcome	PT	70. 40		сопрану кероп мин	ber: 930200	235001	Age: 15 YR	Gen	der: Female
	Dysphonia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Accutane		PS	Roche	ORAL	50	10
Date: 06/08/1995	ISR Number: 1616762-2	Report Type: Periodic			· · · · · ·				10
Outcome	PT		5 98 55	Company Report Num	ber: 940202	390001	Age: 28 YR	Gen	der: Female
	Benign Intracranial	Report Source	Product	<u> </u>	Role	Manufacturer	Route	D 67. 14	1 <u>1</u> 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	Hypertension	Health Professional	Accutane		PS	Roche		Dose/Unit	Duration
	Depression Nec					rodio	ORAL	40	25
	Diplopia								*
	Emotional Disturbance Nos								
late: 06/08/1995	ISR Number: 1616774-9	Report Type: Periodic		C		<del></del>			
Outcome	PT			Company Report Num	er: 9402010	002001	Age: 43 YR	Gen	der: Female
	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		Consumer	Accutane		PS	Roche	ORAL	40	PALAMON
ate: 06/08/1995	ISR Number: 1616784-1	Report Type: Periodic					OKAL	40	
utcome	PT			Company Report Numb	er: 9502002	237001	Age: 17 YR	Gen	der: Male
- inc	Depression Nec	Report Source	Product		Role	Manufacturer			
	Emotional Disturbance Nos	Consumer	Accutane		PS		Route	Dose/Unit	Duration
	AOIM DISHIDARCE NOS				ra	Roche	ORAL.		182

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Date: 06/08/1995	ISR Number: 1616831-7	Report Type: Periodic		Company Report Numbe	9502004	38001	Age: 16 YR	Gen	der: Male
Outcome Disability	PT Blood Alkaline Phosphatase Nos Increased Depression Nec Hyperlipidaemia Nos Vomiting Nos	Report Source  Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 219
Date: 06/08/1995 Outcome	ISR Number: 1616857-3	Report Type: Periodic		Company Report Number	9402020	986001	Age: 14 YR	Gen	ider: Female
Hospitalization -	Abdominal Pain Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Emotional Disturbance Nos Laboratory Test Abnormal Nos Pelvic Pain Nos	Consumer	Accutane Alupent Rynatan Slo-Bid Zoloft		PS C C	Roche	ORAL	60	37
Date: 06/08/1995 Outcome	ISR Number: 1616882-2	Report Type: Periodic Report Source	Product	Company Report Number	: 9502002		Age: 18 YR	Gen	der: Male
·	Impotence Pyrexia	Consumer	Accutane Anacin	line Hydrochloride	Role PS C C	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 1 2
Outcome	ISR Number: 1616890-1  PT  Arthralgia	Report Type: Periodic	Product	Company Report Number		74001 Manufacturer	Age: 14 YR	Gen Dose/Unit	der: Male  Duration
	Asthenia Emotional Disturbance Nos Hypokinesia	Consumer	Accutane Sudafed		PS C	Roche	ORAL	80	41
ate: 06/08/1995	ISR Number: 1616893-7	Report Type: Periodic		Company Report Number	9402020	18001	Age: 15 YR	Gen	der: Male
Dutcome	PT	Report Source	Product						der: Male
	Depression Nec	Health Professional	Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration
nte: 10/13/1994	ISR Number: 1616898-6 PT	Report Type: Periodic		Company Report Number		<del></del>	Age: 27 YR	40 Gen	der: Female
	Amnesia Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Accutane		PS	Roche	ORAL	40	

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Date: 06/08/1995 Outcome	ISR Number: 1616899-8	Report Type: Periodic  Report Source	Product	Company Report Numb		0277001	Age: 19 YR	Gen	nder: Male
·	Depression Nec Emotional Disturbance Nos Personality Disorder Nos	Consumer	Accutane	<u>·</u>	Role PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 1
Date: 06/08/1995 Outcome	ISR Number: 1616904-9	Report Type: Periodic		Company Report Numb	er: 940202	2034001	Age: 44 YR	Cen	ıder: Female
Stateome	PT Headache Nos Insomnia Nec Paranoia Rectal Bleeding	Report Source Consumer	Product Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration 6
Oate: 06/08/1995	ISR Number: 1616906-2	Report Type: Periodic	<del></del>	Company Report Numb	er: 940202	2032001	Age: 20 YR	Gen	nder: Male
	Dysphonia  Laryngeal Neoplasm Nos	Report Source Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
Outcome	ISR Number: 1616909-8	Report Type: Periodic		Company Report Number	er: 950200		Age: 17 YR	40 Gen	169 der: Male
	Agitation Amblyopia Nos Epistaxis	Report Source  Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit 100	Duration 182
ate: 06/08/1995	Hypertension Nos ISR Number: 1616926-8	Report Type: Periodic		Company Report Numbe					
Outcome	PT Constipation Depression Nec Epistaxis Myalgia	Report Source Consumer	Product Accutanc Claritin	Company Report Number	Role PS C	Manufacturer Roche	Route ORAL	Gene Dose/Unit 80	der: Female  Duration
utcome	ISR Number: 1616927-X	Report Type: Periodic		Company Report Numbe	r: 9402020	739001	Age: 32 YR	Gend	der: Female
	Hypersensitivity Nos Nervousness Rash Maculo-Papular Urticaria Nos	Report Source  Health Professional	Product Accutane	<del></del>	Role PS	Manufacturer Roche	Route	Dose/Unit 80	Duration 2
08/03/2000									

# dverse Eveni Reporting System (AERS) Date: 06/08/1995 ISR Number: 1616930-X Report Type: Periodic Company Report Number: 940201278001 Age: 20 YR Gender: Female Outcome PT Report Source Product Hospitalization -Role Dysphonia Dose/Unit Duration Route Health Professional Initial or Prolonged Accutane Laryngitis Nos Roche ORAL 178 Date: 06/08/1995 ISR Number: 1616947-5 Report Type: Periodic Company Report Number: 940202046001 Age: 25 YR Gender: Female Outcome Report Source Product Role Apathy Manufacturer Route Dose/Unit Duration Consumer Dizziness (Exc Vertigo) Accutane PS Roche ORAL Nervousness Sedation Date: 06/08/1995 ISR Number: 1616963-3 Report Type: Periodic Company Report Number: 940201441001 Age: 19 YR Gender: Male Outcome Report Source Product Impotence Role Ronte Dose/Unit Duration Health Professional Accutanc PS ORAL 21 Date: 06/08/1995 ISR Number: 1617014-7 Report Type: Periodic Company Report Number: 940201068001 Age: 25 YR Gender: Female Outcome PT Report Source Product Acne Nos Role Manufacturer Dose/Unit Duration Health Professional Accutane Alopecia PS Roche ORAL 120 Depression Nec Hair Disorder Nos Date: 06/08/1995 ISR Number: 1617018-4 Report Type: Periodic Company Report Number: 940201465001 Age: 31 YR Gender: Female Outcome Report Source Product Role Anaemia Nos Route Dose/Unit Duration Consumer Arthralgia Accutane PS ORAL 41 Depression Nec Desogen С Headache Nos Date: 06/08/1995 ISR Number: 1617030-5 Report Type: Periodic Company Report Number: 940202068001 Age: 14 YR Gender: Female Outcome Report Source Product Role Alopecia Manufacturer Dose/Unit Duration Route Consumer Coordination Abnormal Nos Accutane PS ORAL Dystonia Proventil С Emotional Disturbance Nos

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			readon.	H Information		Report			
Date: 06/08/1995	ISR Number: 1617031-7	Report Type: Periodic		Company Report Numbe	r: 940201	469001	Age: 18 YR	Ger	ıder: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D
	Chest Pain	Health Professional	Accutane		PS	Roche	ORAL	Dose Onit	Duration
	Palpitations Tachycardia Nos		Minocycline		c	ROLLE	ORAL		
Date: 06/08/1995	ISR Number: 1617037-8	Report Type: Periodic		Company Report Numbe		312001	447.170		
Outcome	PT	D			1. 930200	512001	Age: 17 YR	Ger	ider: Female
	Condition Aggravated	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Consumer	Accutane		PS	Roche	ORAL	20.	5
<del></del>			Prozac	<u> </u>	С				1
Outcome	ISR Number: 1617049-4 .PT	Report Type: Periodic		Company Report Numbe	r: 940201	498001	Age: 28 YR	Ger	ıder: Female
Jacome	Palpitations	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Paraesthesia Nec Tachycardia Nos	Health Professional	Accutane		PS	Roche	ORAL	80	5
Date: 06/08/1995	ISR Number: 1617095-0	Report Type: Periodic		Company Report Numbe	r: 940201	022001	Age:	Ger	nder: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	TO 601 44	
	Infection Nos	Consumer	Accutane		PS	Roche	<del></del>	Dose/Unit	Duration
	Myalgia Palpitations			• •	15	Roche	ORAL	30	22
Date: 06/08/1995	ISR Number: 1617112-8	Report Type: Periodic		Company Report Numbe	040001	01200+			
Outcome	PT		Santan er	Company Report Number	F: 940201	013001	Age: 16 YR	Ger	ider: Male
	Amnesia Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	Consumer	Accutane		PS ·	Roche	ORAL	40	121
	Emotional Disturbance Nos								
	Thinking Abnormal Nec								
Pate: 06/08/1995	ISR Number: 1617113-X	Report Type: Periodic		Company Report Number	r: 940201	808001	Age: 36 YR	Ger	ıder: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	Donto	D #	
	Insomnia Nec	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
ate: 06/08/1995	ISR Number: 1617121-9	Report Type: Periodic		Company Report Number			ORAL	80	9
Outcome	PT				. 240201		Age: 21 YR	Ger	der: Female
	Emotional Disturbance Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Accutane						

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Date: 06/08/1995 Outcome	ISR Number: 1617129-3 PT	Report Type: Periodic		Company Report Num	her: 94020	1004001	Age: 18 YR	Ge	nder: Male
	Apathy Dermatitis Exfoliative Nos Vasodilatation	Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit 180	Duration 32
Outcome	ISR Number: 1617141-4	Report Type: Periodic		Company Report Numi	er: 940200	0990001	Age: 27 YR	Ge	nder: Female
	Asthenia Depression Nec Refractive Errors Nos Vasodilatation	Report Source  Consumer	Product Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 10
Date: 06/08/1995	ISR Number: 1617151-7	Report Type: Periodic		Company Report Numb	er: 940202	2079001	Age: 15 YR	Ge	nder: Male
Outcome	PT Depression Nec Headache Nos Hostility	Report Source  Consumer	Product Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 80	Duration 7
Outcome	ISR Number: 1617172-4	Report Type: Periodic	Product	Company Report Numb	er: 950200	338001	Age: 24 YR	Ger	nder: Male
	Asthenia Chest Pain Conversion Disorder	Health Professional	Accutane	7 1 2.4 1	Role PS	Manufacturer Roche	Route	Dose/Unit 80	Duration 128
Date: 06/08/1995	Hyperlipidaemia Nos ISR Number: 1617178-5	Report Type: Periodic							
Outcome	PT Amhythmia Nos	Report Source Consumer	Product	Company Report Numb	er: 940201 <u>Role</u>	Manufacturer	Age: 25 YR	Gen Dose/Unit	ider: Female  Duration
ate: 06/08/1995	Palpitations ISR Number: 1617213-4	Report Type: Periodic	Accutane		PS	Roche	ORAL,	60	93
Outcome	PT Dry Skin	Report Source	Product	Company Report Numb	er: 9502001 Role	361001 Manufacturer	Age: 16 YR Route	Gen Dose/Unit	der: Male
	Lacrimal Disorder Nos Thinking Abnormal Nec	Consumer	Accutane		PS	Roche	ORAL	80	Duration 126
te: 06/08/1995	ISR Number: 1617225-0 PT	Report Type: Periodic		Company Report Number	er: 9502003	371001	Age: 15 YR	Gen	der: Male
	Hallucination Nos Pyrexia	Report Source Health Professional	Product Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration

		Title							
				C Front Report		SISTEMATICAL PROPERTY.			
			10000	Of information		Report			
Date: 06/08/1995	ISR Number: 1617227-4	Report Type: Periodic							
Outcome	PT			Company Report Numb	er: 940200	933001	Age: 36 YR	Ge	ender: Female
	Amnesia Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
<del></del>		Health Professional	Accutane		PS	Roche	ORAL	60	Duration
Date: 06/08/1995	ISR Number: 1617228-6	Report Type: Periodic		C					
Outcome	PT			Company Report Numb	er: 950200	373001	Age: 12 YR	Ge	ender: Female
	Alopecia	Report Source Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Arthralgia	Consumer	Accutane		PS	Roche	ORAL	60	3
	Emotional Disturbance Nos								,
Date: 06/08/1995	Vomiting Nos			_					
Ate: 00/08/1995	ISR Number: 1617351-6	Report Type: Periodic		Company Report Number	940202	142001		<del></del>	<del></del>
Outcome	<u>PT</u>	Report Source	Dundans	passy accepte stanting	11, 940202	142001	Age: 47 YR	Ge	nder: Female
	Palpitations	Health Professional	Product Accutane	<del></del>	Role	Manufacturer	Route	Dose/Unit	Duration
Date: 06/08/1995			Acculance		PS	Roche	ORAL,	40	66
	ISR Number: 1617368-1	Report Type: Periodic		Company Report Number	r: 940202	157001	4		
Outcome	PT	Report Source	Product				Age: 32 YR	Ge	nder: Female
	Headache Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Insomnia Nec Myalgia		Accutant		PS	Roche	ORAL	40	8
ate: 06/08/1995									
	ISR Number: 1617372-3	Report Type: Periodic		Company Report Numbe	r: 940202	154001			
Outcome	PT	Report Source	Product				Age: 11 YR	Ger	nder: Female
	Bone Disorder Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
-t 06 P0 4 20 5	Depersonalisation		. Iconant	_	PS	Roche	ORAL.	40	152
nte: 06/08/1995	ISR Number: 1617390-5	Report Type: Periodic		Company Report Number	- 9402021	67001			<del></del>
outcome	PT	Report Source	Product	I FImine	>402021		Age: 30 YR	Ger	nder: Female
	Depression Nec	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
ite: 06/08/1995			Accutane		PS	Roche			
116: 00/08/1995	ISR Number: 1617397-8	Report Type: Periodic		Company Report Number	0402021	03001			
utcome	PT	Report Source	Danish	And rechare temine	. >-02021	73001	Age: 16 YR	Gen	ader: Pemale
	Emotional Disturbance Nos	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Weight Decreased		Accutane		PS	Roche	ORAL	50	43

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Date: 06/08/1995	ISR Number: 1617431-5	Report Type: Periodic		Company Report Numb	er: 940202	179001	Age: 16 YR	Gen	der: Male
Outcome	РТ	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec Emotional Disturbance Nos Personality Disorder Nos	Health Professional	Accutane		PS	Roche	ORAL,	50	Duration
Date: 06/08/1995	ISR Number: 1617445-5	Report Type: Periodic		Company Report Numb	er: 940202	414001	Age: 38 YR	Gen	der: Female
Outcome	PT	Report Source	Product	*	Role	Manufacturer	Route	D	
	Amnesia Nec	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit 60	Duration
Date: 06/08/1995	ISR Number: 1617457-1	Report Type: Periodic		Company Report Numb	er: 940202	423001	Age: 28 YR	Gen	ider: Female
Outcome	PT	Report Source	Product		Dala	Monutestania			
	Cerebral Oederna	Consumer	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
	Conjunctivitis Nec				гэ	Roche	ORAL	10	1
	Depression Nec Headache Nos								
Date: 06/08/1995	ISR Number: 1617466-2	Report Type: Periodic		Company Report Numb	er: 940202	443001	Age: 28 YR	Gen	ıder: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	D4-	D 27.11	
	Arthralgia Myalgia Palpitations	Health Professional	Accutane	-	PS	Roche	ORAL.	Dose/Unit 60	Duration
Date: 06/08/1995	ISR Number: 1617719-8	Report Type: Periodic	er (1	Company Report Number	er: 940201	014001	Age: 20 YR	Gen	der: Female
Outcome	PT	Report Source	Product				_		
	Agitation	Health Professional	Accutane	<del></del>	Role PS	Manufacturer	Route	Dose/Unit	Duration
Date: 06/08/1995	ISR Number: 1617821-0		·			Roche	ORAL	40	52
		Report Type: Periodic		Company Report Number	er: 940200	960001	Age: 35 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Antimuclear Factor Positive Back Pain	Health Professional	Accutane		PS	Roche	ORAL	120	117
	Emotional Disturbance Nos Headache Nos						ORIL		11/
Date: 06/08/1995	ISR Number: 1617833-7	Report Type: Periodic		Company Report Number	er: 940200	965001	Age: 42 YR		der: Female
Outcome	PT	Report Source	Product				-	Gen	uer. Female
	Benign Intracranial	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Hypertension Emotional Disturbance Nos		Accurane		PS	Roche	ORAL	40	215

# Adverse Event Reporting System (ATRS Freedom Of Information (FOI) Report Date: 06/08/1995 ISR Number: 1622453-4 Report Type: Periodic Company Report Number: 950200390001 Age: 34 YR Gender: Male Outcome Report Source Product Impotence Manufacturer Route Dose/Unit Duration Health Professional Testicular Disorder Nos Accutane Roche ORAL 1 Date: 06/08/1995 ISR Number: 1622463-7 Report Type: Periodic Company Report Number: 950200392002 Age: 43 YR Outcome Gender: Male Report Source Product Other Impotence Role Manufacturer Route Dose/Unit Duration Health Professional PS Roche ORAL 60 Date: 06/08/1995 ISR Number: 1622466-2 Report Type: Periodic Company Report Number: 950200392001 Age: 23 YR Gender: Male Outcom Report Source Product Other Impotence Role Manufacturer Route Dose/Unit Duration Health Professional Accutane PS ORAL 67 Date: 06/08/1995 ISR Number: 1622481-9 Report Type: Periodic Company Report Number: 940201517001 Age: 40 YR Gender: Female Outcome Report Source Product Insomnia Nec Role Manufacturer Health Professional Dose/Unit Duration Nervousness Accutane PS ORAL 79 Paraesthesia Nec Date: 06/08/1995 ISR Number: 1622498-4 Report Type: Periodic Company Report Number: 940201529001 Age: 15 YR Gender: Female Outcome Report Source Product Acne Nos Dose/Unit Duration Health Professional Accutane Asthenia PS ORAL. 154 Depression Nec Otitis Media Nos Date: 06/08/1995 ISR Number: 1622508-4 Report Type: Periodic Company Report Number: 950200423001 Age: 18 YR Outcome Gender: Male Report Source Product Depression Nec Role Manufacturer Route Dose/Unit Duration Dermatitis Nos PS Roche 185 Hyperaesthesia Vasodilatation Date: 06/08/1995 ISR Number: 1622511-4 Report Type: Periodic Company Report Number: 940201566001 Age: 7 YR Outcome Gender: Female PT Report Source Abnormal Dreams Role Manufacturer Route Health Professional Dose/Unit Duration Accutane Tooth Discolouration PS ORAL

# FDA : Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report

Date: 06/08/1995	ISR Number: 1622512-6	Report Type: Periodic		Company Report Number: 95020	0422002	Age: 24 YR	Ge	nder: Female
Outcome	PT	Report Source	Product	Role	Manufacture			
	Acne Nos Condition Aggravated Depression Nec	Consumer	Accutane	PS	Manufacturer Roche	Route ORAL	Dose/Unit	Duration 79
Date: 06/08/1995	ISR Number: 1622534-5	Report Type: Periodic		Company Report Number: 94020	1597001	Age: 31 YR		ıder: Female
Outcome	PT	Report Source	Product			inger STIR	. Ge	ider: Female
	Palpitations	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit	Duration
	Tachycardia Nos		Prozac	PS	Roche	ORAL,	80	43
Date: 06/08/1995	ISR Number: 1622576-X	Report Type: Periodic	riozac	C Company Report Number: 94020	1601001			<del></del>
Outcome	PT	D		company report runner; 94020	1621001	Age: 15 YR	Ger	ider: Male
	Gingivitis	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	Metal Poisoning Palpitations	Health Professional	Accutane	PS	Roche	ORAL		39
Date: 06/08/1995	ISR Number: 1622634-X	Report Type: Expedited (	(15-Day)	Company Report Number: 950200	1467001	Age: 16 YR	Ga	ider: Female
Outcome	PT PT	Report Source	Product	Ti_i_	Mountostus	- ·		
Disability	Conversion Disorder	Health Professional	Accutane	Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
	Depression Nec Headache Nos		••	ra	Roche	ORAL	80	28
	Syncope							
Date: 06/08/1995	ISR Number: 1622665-X	Report Type: Periodic		Company Report Number: 940201	693001	Age: 39 YR	Ger	ider: Male
Outcome	PT	Report Source	Product	n-I-		_		Minte
	Impotence	Health Professional	Accutane	Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
Date: 06/08/1995	ISR Number: 1622666-1	Report Type: Periodic				ORAL		
Outcome	PT			Company Report Number: 940201	705001	Age: 21 YR	Gen	der: Female
- Cartonic	Depression Nec	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
	- V	Health Professional	Accutane	PS	Roche	ORAL	20	32
			Erythromycin	C				36
			Hytone	c				
D. A. Ocionus			Ortho-Cept	С	_			
Oate: 06/08/1995	ISR Number: 1622767-8	Report Type: Periodic		Company Report Number: 950200	496001	Age: 24 YR	Gen	der: Female
Outcome	PT Agitation	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration

		FDA	Additions for	d Reporting Sys	tem (A.E.R.S)			
		1	rectors (if In	formation (FCI)	Report			
Date: 06/08/1995	ISR Number: 1622771-X	Report Type: Periodic	Commo	== D===4 N==1	501001			
Outcome	PT			ny Report Number: 950200	501001	Age:	Gen	ider: Female
	Insomnia Nec	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	Duration
·	Nervousness	Consumer	Accutane	PS	Roche	ORAL	**	
Date: 06/08/1995	ISR Number: 1622809-X	Report Type: Periodic	Compa	ny Report Number: 950200	514001	Age: 17 YR	Ger	ıder: Male
Outcome	PT	Report Source	Product			1,11	Otal	Maje
Other	Amnesia Nec	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit	Duration
			Accurate	PS	Roche	ORAL		
Date: 06/08/1995	ISR Number: 1622817-9	Report Type: Periodic	Compa	ny Report Number: 950200	080001	Age: 22 YR	Gen	ıder: Male
Outcome	PT	Report Source	Product	Role	16	_		
	Depression Nec	Consumer	Accutane	PS	Manufacturer Roche	Route	Dose/Unit	Duration
	Drug Withdrawal Syndrome				коспе	ORAL		185
Date: 06/08/1995	ISR Number: 1622848-9	Report Type: Periodic	Compa	ny Report Number: 950200	090001	Age: 29 YR	Gen	ıder: Male
Outcome	PT	Report Source	Product			•	Gai	idei. Maje
	Libido Decreased	Consumer	Accutane	Role	Manufacturer	Route	Dose/Unit	Duration
	<del></del>	<del></del>	Tiocounic	PS	Roche	ORAL	40	106
Date: 06/08/1995	ISR Number: 1622892-1	Report Type: Periodic	Compa	ny Report Number: 950200	111001	Age: 15 YR	Ger	nder: Male
Outcome	PT	Report Source	Product				Gui	idel. Maje
	Depression Nec	Health Professional	Accutane	Role PS	Manufacturer	Route	Dose/Unit	Duration
	Granuloma Nos		·	rs ·	Roche	ORAL	80	90
	Skin Hypertrophy Weight Decreased							
Date: 06/08/1995			-					
Sacc. 00/00/1993	ISR Number: 1622982-3	Report Type: Periodic	Сотра	ny Report Number: 950200	185001	Age: 29 YR	Gen	ıder: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	D4-	Y	
	Depression Nec	Consumer	Accutane	PS	Roche	Route	Dose/Unit	Duration
Date: 06/08/1995	TODAY A CORNER	<del></del>			ROCAL	ORAL	80	182
	ISR Number: 1623067-2	Report Type: Periodic	Compa	ny Report Number: 950200:	598001	Age: 18 YR	Gen	ider: Female
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	
	Cheilitis Dry Skin	Consumer	Accutane	PS	Roche	ORAL		Duration
	Emotional Disturbance Nos		Aloe	c		OKAL	20	31
	Peripheral Vascular Disease Nos		Vitamin B Complex	c				
			Vitamin E	С				

		FDA :		Event-Reporti		tem (Albika)			
		, F	recion.	Of Information		Remort			
Date: 06/08/1995	ISR Number: 1623765-0	Report Type: Periodic		Company Report Numb	er: 940202	430001	Age: 23 YR	Gen	ider: Male
Outcome	<u>PT</u>	Report Source	Product		Role	Manufacturer	Route		
	Acue Nos Depression Nec Drug Ineffective	Consumer	Accutane		PS	Roche	ORAL	Dose/Unit	Duration
Date: 06/08/1995	ISR Number: 1623809-6	Report Type: Periodic		Company Report Number	er: 950200	003001	Age: 30 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer			
	Asthenia Emotional Disturbance Nos	Health Professional	Accutane		PS	Roche	Route ORAL	Dose/Unit	Duration
	Headache Nos Hypoaesthesia		Demulen		C	Toge	ORAL	40	26
Date: 06/08/1995	ISR Number: 1623859-X	Report Type: Periodic		Company Report Number	r: 950200	060001	Age: 29 YR	Gen	der: Female
Outcome	PT	Report Source	Product		D.1.		-		
	Nervousness Rigors Sweating Increased	Consumer	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit 80	Duration
Date: 06/08/1995	Vasodilatation	·	· · ·						
	ISR Number: 1623875-8	Report Type: Periodic		Company Report Number: 950200062001			Age: 18 YR	Gen	der: Female
Outcome	PT Anorexia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos Vomiting Nos Weight Decreased	Consumer	Accutane Vitamins		PS C	Roche	ORAL	40	152
Date: 06/08/1995	ISR Number: 1623877-1	Report Type: Periodic		Company Report Numbe	r: 9502000	086001	Age: 27 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Dole	Manufacture			212112
	Alopecia Cheilitis	Consumer	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
	Depression Nec		Alcohol		SS	- Adio	ORAL	40	123
<del></del>	Dry Skin								
Date: 07/31/1995	ISR Number: 1624202-2	Report Type: Expedited (1	5-Day)	Company Report Numbe	r: 48073		Age: 23 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacturer	-		T.MIO
Death	Suicide Attempt	Foreign Health Professional	Roaccutane		PS	Roche	Route ORAL	Dose/Unit	Duration 366

			Teledicing	i i vent Repo Of Intornati	HINESYS Marketon	tem (Al.RS) Report			
Date: 09/19/1995	ISR Number: 1641671-2	Report Type: Expedited	(15-Day)	Company Report N	mber: 49144		Age: 3 YR	0-	ider: Female
Outcome	PT	Report Source	Product					Gen	nder: Female
Hospitalization -	Haemorrhagic Stroke	Foreign	Roaccutane		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Headache Nos		Roaccutane	*	PS	Roche	ORAL	10	677
	Nausea Personality Disorder Nos								
T) 4 00 110 110 11		<del></del>							
Date: 09/19/1995	ISR Number: 1643903-3	Report Type: Expedited	(15-Day)	Company Report Nu	mber: 48312		Age: 16 YR	Corr	nder: Male
Outcome	PT	Report Source	Product				•	o a	ider: Male
Other	Hostility	Health Professional	Accutane	· — — · — · — · — · — · — · — · — · — ·	Role	Manufacturer	Route	Dose/Unit	Duration
	Non-Accidental Injury		Acculatie		PS	Roche	ORAL	60	
	Personality Disorder Nos								
Date: 09/19/1995	ISR Number: 1644960-0	Report Type: Expedited	(15-Day)	Company Report Nu	mber: 50851		Age: 18 YR		
Outcome	PT	Report Source	Product	1			Age: 18 YK	Gen	nder: Female
Hospitalization -	Depression Nec	Foreign			Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Suicide Attempt	Health Professional	Roaccutane		PS	Roche	ORAL .	25	113
			Cyproterone Ethinyl Estr		C				
Date: 09/19/1995	TOD N. A. ACAMORA A.	<del></del>		imor —	С				
Dutt. 03/19/1993	ISR Number: 1644980-6	Report Type: Expedited	(15-Day)	Company Report Nu	mber: 50853		Age: 28 YR	Gen	ider: Female
Outcome	PT	Report Source	Product		D.1.	Manufactur	_ :		
Life-Threatening	Depression Nec	Foreign	Roaccutane		Role_ PS	Manufacturer	Route	Dose/Unit	Duration
Hospitalization -	Suicide Attempt	Health Professional	Lexomil		C	Roche	ORAL	35	206
Initial or Prolonged			Ludiomil		C				
Date: 09/29/1995	ISR Number: 1649674-9	Deposit Town Down		<del> </del>			· · · · · · · · · · · · · · · · · · ·		
0-4		Report Type: Expedited	(15-Day)	Company Report Nu	mber: 45948		Age: 19 YR	Gen	ider: Male
Outcome	PT Confusion	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged	Contusion  Depersonalisation	Foreign	Roaccutane		PS	Roche	ORAL	20	
,	Personality Disorder Nos	Health Professional	Cannabis		С		OME	20	201
· · · · · · · · · · · · · · · · · · ·	Schizophrenia Nos								
Date: 10/03/1995	ISR Number: 1651791-4	Report Type: Expedited	(15-Day)	Company Report Nu	5140°		<del></del>		
Outcome	PT	,	-	Company Report Nu	moer: 31403		Age: 23 YR	Gen	der: Female
Life-Threatening	Non-Accidental Overdose	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Suicide Attempt	Foreign Health Professional	Roaccutane		PS	Roche	ORAL		120
	Unintended Pregnancy	ricatui rroressional	Lysanxia		SS		ORAL		
			Trinordiol		С				

		FDA -	Advers	Event Report	ng syr	tem (All ES)				
			evitori.	Of Information	(10)	Report				
Date: 10/23/1995	ISR Number: 1663144-3	Report Type: Expedited (	15-Day)	Company Report Numb	er: 52115		Age:	Gen	der: Male	
Outcome	PT	Report Source	Product		D.1	35	_		21202	
Hospitalization - Initial or Prolonged	Hallucination Nos Psychotic Disorder Nos	Foreign Health Professional	Roscotane	· · · · · · · · · · · · · · · · · · ·	PS	Manufacturer Roche	Route ORAL	Dose/Unit 40	Duration 7	
Date: 10/27/1995	ISR Number: 1663233-3	Report Type: Expedited (	(5-Day)	Company Report Numb	er: 50223	<u> </u>	Age: 15 YR	Gen	der: Male	
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Demonstra	
Other	Asthenia Depression Nec Emotional Disturbance Nos	Health Professional	Accutane Claritin		PS C	Roche	ORAL	80	Duration 228	
	Suicide Attempt		Paxil		c					
Date: 11/07/1995	ISR Number: 1664531-X	Report Type: Expedited (	5-Day)	Company Report Numb	er: 52660		Age: 19 YR	Gen	der: Male	
Outcome	PT	Report Source	Product		Role	Manufacturer	Dont			
Hospitalization - Initial or Prolonged	Depression Nec Hallucination Nos Paranoia	Consumer	Accutane		PS	Roche	Route	Dose/Unit	Duration 366	
	Schizophrenia Nos									
Date: 10/31/1995	ISR Number: 1665438-4	Report Type: Expedited (1	5-Day)	Company Report Numb	er: 52563		Age: 17 YR	Gen	der: Female	
Outcome	PT	Report Source	Product		Role	Manufacturer	÷.			
Life-Threatening	Non-Accidental Overdose	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration	•
	Suicide Attempt Thinking Abnormal Nec		Tylenol W/0	Codeine No. 3	SS	R W Johnson	ORAL	80	141 1	
Date: 11/13/1995	ISR Number: 1671043-6	Report Type: Expedited (1	5-Day)	Company Report Numb	er: 52947		Age: 22 YR	Gen	der: Male	
Outcome	PT	Report Source	Product		Role	No	_			
Death	Hepatic Function Abnormal Nos	Consumer	Accutane		PS	Manufacturer	Route	Dose/Unit	Duration	
	Non-Accidental Injury Suicide Attempt				13	Roche	ORAL			
Date: 12/05/1995	ISR Number: 1682383-9	Report Type: Expedited (1	5-Day)	Company Report Numb	er: 53857		Age: 17 YR	Gen	der: Male	
Outcome	PT	Report Source	Product		Role	Manufacturer	Dont			
Life-Threatening	Asthenia	Foreign	Roaccutane		PS	Roche	Route	Dose/Unit	Duration	
Hospitalization - Initial or Prolonged	Depression Nec Insomnia Nec	Health Professional			10	Roche	ORAL		107	
	Suicide Attempt									

		T	estation.	: Event Repor Of Informatio		tem Aliks) Remort			
Date: 01/18/1996	ISR Number: 1691903-X	Report Type: Expedited (		Company Report Nur			Age: 29 YR		
Outcome	PT	Report Source	Day day 4				Age. 29 1 K	Gen	der: Female
Life-Threatening	Depression Nec	Foreign	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Hospitalization -	Suicide Attempt	Health Professional	Roaccutane		PS	Roche	ORAL	35	206
Initial or Prolonged			Lexomil Ludiomil		SS	Upjohn	ORAL	18	
					С.				
Date: 01/30/1996	You by the second	<del></del>	Maprotiline		С				
Outcome	ISR Number: 1700773-2 PT	Report Type: Expedited (	15-Day)	Company Report Num	ıber: 56829		Age: 19 YR	Gen	der: Male
Life-Threatening	Suicide Attempt	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		Foreign Health Professional	Roaccutane		PS	Roche	ORAL		122
Date: 02/27/1996	ISR Number: 1713235-3	Report Type: Expedited (	I5-Day)	Company Report Num	ber: 58392		Age: 20 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer			_
Life-Threatening	Amnesia Nec	Foreign	Accutane		PS PS	Roche	Route	Dose/Unit	Duration
Hospitalization - Initial or Prolonged Disability	Major Depressive Disorder Nos Thinking Abnormal Nec	Health Professional				Koale	ORAL		62
Date: 02/23/1996	ISR Number: 1718090-3	Report Type: Expedited (1	5-Day)	Common Do (N)			· · ·		
Outcome	PT .			Company Report Nun	IDer: 3/993		Age: 16 YR	Gen	der: Female
Hospitalization -	Aphasia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Cerebral Artery Thrombosis Headache Nos Hemiplegia	Foreign	Roaccutane		PS	Roche	ORAL		150
Date: 03/06/1996	ISR Number: 1720890-0	Description of the second							
0-4		Report Type: Expedited (1	ე-⊔ay)	Company Report Num	ber: 58625		Age: 17 YR	Gen	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D41
Hospitalization - Initial or Prolonged	Aphasia Cerebral Artery Thrombosis	Foreign	Roaccutane		PS	Roche	ORAL		Duration
	Headache Nos	Health Professional					UKAL,	20	89
	Hemiplegia								
Date: 04/30/1996	ISR Number: 1745385-X	Report Type: Expedited (1	5-Day)	Company Report Num	ber: 61784		Age:	Gen	der: Male
Outcome	PT	Report Source	Product				•		uer. Maie
Life-Threatening	Suicide Attempt	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
			, recutant		PS	Roche	ORAL		

### Date: 04/30/1996 ISR Number: 1747358-X Report Type: Direct Company Report Number: Age: 22 YR Gender: Male Outcome Report Source Product Manufacturer Route Dose/Unit Duration Suicide Attempt Death Health Professional PS 37 Date: 06/13/1996 ISR Number: 1763027-4 Report Type: Periodic Company Report Number: 950200692001 Age: 18 YR Gender: Male Report Source Role Manufacturer Route Dose/Unit Duration Other Anxiety Nec Health Professional Accutane PS Roche Insomnia Nec 158 Kenalog С 1 Date: 06/13/1996 ISR Number: 1763037-7 Report Type: Periodic Company Report Number: 950200685001 Age: 21 YR Gender: Male Outcome Report Source Product Role Manufacturer Other Agitation Dose/Unit Duration Accutane PS Roche Condition Aggravated ORAL. 80 22 Ritalin C Date: 06/18/1996 ISR Number: 1763058-4 Report Type: Expedited (15-Day) Company Report Number: 63060 Age: 21 YR Gender: Female Outcome Report Source Product Role Manufacturer Route Dose/Unit Duration Hospitalization -Suicide Attempt Foreign Roaccutane Initial or Prolonged PS Roche ORAL Health Professional Trinordiol Date: 06/13/1996 ISR Number: 1763094-8 Report Type: Periodic Company Report Number: 950200643001 Age: 34 YR Gender: Female Report Source Product Role Manufacturer Route Dose/Unit Duration Dyspareunia Nec Consumer Epistaxis PS. ORAL 118 Headache Nos Vaginal Discharge Date: 06/13/1996 ISR Number: 1763098-5 Report Type: Periodic Company Report Number: 950200636001 Age: 15 YR

Role

PS

С

Role

PS

Company Report Number: 950200621001

Manufacturer

Manufacturer

ORAL

Age: 29 YR

Route

ORAL

Roche

Report Source

Health Professional

Report Type: Periodic

Report Source

Emotional Disturbance Nos

ISR Number: 1763106-1

Bone Disorder Nos

Depression Nec

Product

Accutane

Product

Accutane

Erythromycin

Outcome

Date: 06/13/1996

Other

Outcome

Other

Gender: Female

Gender: Female

Dose/Unit Duration

Dose/Unit Duration

80

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			rosion	Of Informati	0100000	Report			
Date: 06/13/1996	ISR Number: 1763108-5	Report Type: Periodic		-					
Outcome	PT	-		Company Report N	umber: 950200	620001	Age: 29 YR	Ge	nder: Female
Other	Alopecia	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Condition Aggravated	Consumer	Accutane		PS	Roche	ORAL		Duration
	Emotional Disturbance Nos		Amitriptyl	ine	C	***************************************	OKAL	- 80	
Date: 06/13/1996	ISR Number: 1763402-8	Report Type: Periodic	-	C		<del></del>			
Outcome	PT			Company Report N	umber: 950200	678001	Age: 16 YR	Ge	nder: Male
Disability	Cheilitis	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	D
•	Depression Nec	Consumer	Accutane		PS	Roche	ORAL		Duration
	Epistaxis						ORAL	80	
	Vomiting Nos								
Date: 06/13/1996	ISR Number: 1767948-8	Report Type: Periodic	<del></del>	~ -					
Outcome	PT			Company Report Nu	ımber: 51642		Age:	Ge	nder: Unknown
Other	Emotional Disturbance Nos	Report Source	Product		Role	Manufacturer	Route		
		Health Professional	Accutane	100	PS	Roche	ORAL	Dose/Unit	Duration
Date: 06/13/1996	ISR Number: 1769065-X	Daniel W. D. L.					ORAL		
Outcome		Report Type: Periodic		Company Report Nu	mber: 61373		Age: 28 YR	Ge	nder: Female
Other	PT Almost	Report Source	Product		Role	Manuel			- Chiare
Cinc	Alopecia Anxiety Nec	Health Professional	Accutane		PS	Manufacturer	Route	Dose/Unit	Duration
	Dry Skin				ra	Roche	ORAL	40	71
	Tachycardia Nos								
Date: 06/13/1996	ISR Number: 1769070-3								
_	1014 Hunther: 1709070-3	Report Type: Periodic		Company Report Nu	mber: 9502006	86001	Age:		
Outcome	PT	Report Source	Product				Age.	Ger	nder: Male
Other	Emotional Disturbance Nos	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
			Accutane		PS	Roche	ORAL	40	
late: 06/13/1996	ISR Number: 1769071-5	Report Type: Periodic		Company Report Nu	1 40005				
Outcome	PT	Demont C.	_		miner: 43983		Age: 18 YR	Ger	ıder: Male
Other	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	<u> </u>	Health Professional	Accutane		PS	Roche	ORAL		91
ate: 06/13/1996	ISR Number: 1769081-8	Report Type: Periodic							71
Outcome	PT			Company Report Nu	mber: 52188		Age: 18 YR	Ger	ider: Female
Iospitalization -	Chest Pain	Report Source	Product		Role	Manufacturer	Route	D #1 1	
itial or Prolonged	Hypotension	Health Professional	Accutane		PS	Roche		Dose/Unit	Duration
-	Palpitations		Nyquil		C	Koche	ORAL	40	51
	Tachycardia Nos		Desogen		_				1

08/03/2000

			reserve on	r Exent Report Of Information		teni (ALEES) Roman				
Date: 06/13/1996	ISR Number: 1769088-0	Report Type: Periodic		Company Report Numb						
Outcome	PT	Dan and St.			CI; 4/313		Age: 16	YR	Gender: Female	e
Other	Hostility	Report Source	Product		Role	Manufacturer	Route	Dose/Ur	it Duration	
	Mania	Health Professional	Accutane		PS	Roche	ORAL			-
	Nervousness		Demnica		С		OKAL.	60	122	
	Thinking Abnormal Nec		Anaprox		C					
Date: 06/13/1996	ISR Number: 1769139-3	Report Type: Periodic	<del></del>	Company Report Numb	er: 55348		Age: 35			
Outcome	PT	Report Source	Product				Age: 33	YK	Gender: Male	
Other .	Impotence	Health Professional			Role	Manufacturer	Route	Dose/Un	it Duration	
<del></del>		Treatur Frotessionar	Accutane		PS	Roche	ORAL	10		-
Date: 06/13/1996	ISR Number: 1769374-4	Report Type: Periodic		Company Report Number	er: 56892		Age: 14	<del></del>	Gender: Male	
Outcome	PT	Report Source	Product				<b>y</b>		ounce. Male	
Other	Personality Disorder Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Un	it Duration	_
D.4. 06#8#8#	<del></del>		riccutatie		PS	Roche	ORAL	40	62	
Date: 06/13/1996	ISR Number: 1769385-9	Report Type: Periodic		Company Report Numbe	56020		<del></del>		<del></del>	
Outcome	PT	Th		Company Report Number	T: 3083U		Age: 19	YR	Gender: Female	
Other	Dysphonia	Report Source	Product		Role	Manufacturer	Route	Dose/Un	it Duration	
		Health Professional	Accutane		PS	Roche	ORAL		R Duration	-
Date: 06/13/1996	ISR Number: 1769404-X			<del></del>			ORAL	60		
	·-	Report Type: Periodic		Company Report Numbe	r: 57286		Age: 26	YR	Gender: Female	•
Outcome	PT	Report Source	Product				1.5.		Gender: Female	•
Other	Personality Disorder Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Un	it Duration	
					PS	Roche	ORAL	40	215	
Date: 06/13/1996	Top at		Kenalog		С					
June: 00/15/1990	ISR Number: 1769411-7	Report Type: Periodic		Company Report Numbe	r: 57202					
Outcome	_ PT	Report Source		Tany onepote transpe	1. 57292		Age: 33 Y	rr.	Gender: Female	
Other	Dysphonia		Product		Role	Manufacturer	Route	Dose/Un	lt Duration	
		Health Professional	Accutane		PS	Roche	ORAL,		182	
			Zoloft		С				182	
			Retin-A		С					
ate: 06/13/1996	ISR Number: 1769472-5	Report Type: Periodic		Comment Day 125						
Outcome	PT			Company Report Number	r: 57845		Age: 16 Y	R (	Gender: Male	
ther	Agitation	Report Source	Product		Role	Manufacturer	Route	D ~~		
	Emotional Disturbance Nos	Health Professional	Accutane		PS	Roche		Dose/Uni	t <u>Duration</u>	
	Personality Disorder Nos					Rodie	ORAL	60	142	

	Dermatitis Nos Emotional Disturbance Nos Pruritus	Consumer	Accutane	PS	Roche	ORAL	Dose/Unit	Duration
utcome ther	PT Alopecia	Report Source	Product	Company Report Number: 49468	Manufacturer	Age:	Gen Dose/Unit	der: Female
ate: 06/13/1996	ISR Number: 1769689-X	Report Type: Periodic	- iccitatie	PS Company Parant V	Roche	ORAL	60	85
Other	PT Depression Nec	Report Source Health Professional	Product Accutane	Role	Manufacturer	Route	Dose/Unit	Duration
ate: 06/13/1996	ISR Number: 1769623-2	Report Type: Periodic		Company Report Number: 48842		Age: 17 YR		ider: Male
Other	Amnesia Nec Personality Disorder Nos	Health Professional	Accutane	Role PS	Manufacturer Roche	Route	Dose/Unit	Duration 108
Outcome	ISR Number: 1769592-5	Report Type: Periodic  Report Source	Product	Company Report Number: 48220		Age: 19 YR	Ger	nder: Female
Pate: 06/13/1996	Depression Nec	Consumer	Accutane	PS	Manufacturer Roche	Route ORAL	Dose/Unit 50	Duration
Outcome Other	PT Agitation	Report Source	Product	Company Report Number: 58218		Age:		nder: Female
ate: 06/13/1996	ISR Number: 1769518-4	Report Type: Periodic		c		· · · · · · · · · · · · · · · · · · ·		
	Emotional Disturbance Nos Seborrhoea		Unipres Xanax	PS C	Roche	ORAL	120	150
Other	Conjunctivitis Nec Dermatitis Bullous	Report Source Consumer	Product Accutane	Role	Manufacturer	Route	Dose/Unit	Duration
Date: 06/13/1996 Outcome	ISR Number: 1769503-2	Report Type: Periodic		Company Report Number: 5804	2	Age: 42 YR	Ge	nder: Male
	Tooth Disorder Nos Urine Abnormal Nos Vaginal Discharge	Consumer	Accutane	PS	Roche	ORAL	40	121
Outcome Other	PT Amnesia Nec	Report Source	Product	Role	Manufacturer	Route	Dose/Unit	nder; Female  Duration
_	ISR Number: 1769482-8	Report Type: Periodic		Company Report Number: 5790	0	Age: 30 YR		

Date: 06/13/1996	ISR Number: 1771002-9		revien	e Event Reporting S Of Information (FO	D Report			
Outcome		Report Type: Periodic		Company Report Number: 5054	8	Age: 37 YR	Gender:	Female
Other	PT Depression Nec	Report Source	Product	Role	Manufacturer			гсшате
	Depression Nec	Health Professional	Accutane	PS	Roche	Ronte	Dose/Unit Du	ration
Date: 06/13/1996	ISR Number: 1771105-9				Rodie	ORAL	118	3
Outcome		Report Type: Periodic		Company Report Number: 4670	2	Age: 25 YR	Gender:	
Other	PT	Report Source	Product				Gender:	Female
Outer .	Anxiety Nec Condition Aggravated	Consumer	Accutane	Role	Manufacturer	Route	Dose/Unit Du	ration
	Depression Nec		Ativan	PS	Roche	ORAL	20 65	
	Headache Nos			С				
Date: 06/13/1996	ISR Number: 1771152-7	<del></del>						
	2014 (Manufact: 1//1152-/	Report Type: Periodic		Company Report Number: 53831		Age: 17 YR		
Outcome	PT	Report Source	Product			Age: 1/ IR	Gender:	Female
Hospitalization - Initial or Prolonged	Depression Nec	Health Professional	Accutane	Role	Manufacturer	Route	Dose/Unit Dur	ration
	Headache Nos Мепотhаgia		riccutance	PS	Roche	ORAL	50 157	,
	Proritus							
Date: 06/13/1996	ISR Number: 1771157-6	Report Type: Periodic	<del></del>		<del></del>			
Outcome	PT	,		Company Report Number: 47029		Age: 15 YR	Gender:	Female
Other	Dysphonia	Report Source	Product	Role	Manufacturer	Route	D	
	Laryngitis Nos	Health Professional	Accutane	PS	Roche	ORAL		ation
	Pharyngitis Nos					OKAL	60	
Date: 06/13/1996	ISR Number: 1771230-2	Report Type: Periodic						
Outcome	PT			Company Report Number: 46616		Age: 15 YR	Gender:	Male
Other	Depression Nec	Report Source	Product	Role	Manufacturer	Route	Dose/Unit Dur	
	Emotional Disturbance Nos	Health Professional	Accutane	PS	Roche	ORAL		ation
ate: 06/13/1996	ISR Number: 1771265-X					ORAL	80 173	
<b></b>		Report Type: Periodic		Company Report Number: 46069	·	Age: 19 YR		
Outcome	PT	Report Source	Product			75 17 IK	Gender:	Female
Mer	Emotional Disturbance Nos Melaena	Consumer	Accutane	Role	Manufacturer	Route	Dose/Unit Dur	ation
			Ventolin	PS	Roche	ORAL	80	
te: 06/13/1996	ISR Number: 1771285-5		· wandin	C C				
utcome		Report Type: Periodic		Company Report Number: 43952		Age: 16 YR	Cond	
ther	PT	Report Source	Product	4.5			Gender:	Male
unca	Agitation	Consumer	Accutane	Role	Manufacturer	Route	Dose/Unit Dura	tion
	Emotional Disturbance Nos Hostility		. zooutane	PS	Roche	ORAL	40	

		FDA		Event Repartin		30000 F. VIDE 400			
			readon	Of Information (		Report			
Date: 06/13/1996	ISR Number: 1771325-3	Report Type: Periodic		Company Report Number:	45046		Age: 32 YR		
Outcome	PT PT	Report Source	Product				32 IK	Ge	nder: Female
Other	Arthralgia Emotional Disturbance Nos	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Headache Nos				PS	Roche	ORAL	40	
	Pain Nos								
Date: 06/13/1996	ISR Number: 1771347-2								
Outcome		Report Type: Periodic		Company Report Number:	44941		Age: 48 YR	C	nder; Male
Other	PT Back Pain	Report Source	Product				-	Ge	nder: Male
Ouler	Depression Nec	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec		Capoten		PS -	Roche	ORAL	80	
			Clindamycin		2				
Date: 06/13/1996	ISR Number: 1771361-7	Report Type: Periodic		<del></del>					
Outcome	PT	Report Type: Penodic		Company Report Number:	51284		Age:	Ger	ıder: Female
Other	Depression Nec	Report Source	Product		Role	Manufacturer	D4		
·		Health Professional	Accutane		s	Roche	Route	Dose/Unit	Duration
Date: 06/13/1996	ISR Number: 1771372-1	P		<u> </u>		ROME	ORAL	40	112
Outcome		Report Type: Periodic		Company Report Number:	51460		Age: 17 YR	Ger	ıder: Male
Other	PT Depression Nec	Report Source	Product	,	)_1_			- Gu	tuel. Male
	Depression Nec	Health Professional	Accutane		Role_ S	Manufacturer	Route	Dose/Unit	Duration
ate: 06/13/1996	ISR Number: 1771379-4		<del></del>		3	Roche	ORAL	80	121
Outcome		Report Type: Periodic		Company Report Number:	14384		Age: 16 YR		
Other	PT PT	Report Source	Product	_			age. 10 IK	Gen	ider: Male
uter	Thinking Abnormal Nec	Health Professional	Accutane		lole	Manufacturer	Route	Dose/Unit	Duration
			Ventolin		S	Roche	ORAL		97
ete: 06/13/1996	ISR Number: 1771404-0	Penert True D	<del></del>						
utcome		Report Type: Periodic		Company Report Number:	13915		Age: 15 YR	Con	der: Male
ther	PT Conjunctivitis Nec	Report Source	Product		ole	Manufact	-		MINIS.
	Depression Nec	Consumer	Accutane	P		Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos			P		Roche	ORAL	40	147
	Thinking Abnormal Nec								
te: 06/13/1996	ISR Number: 1771508-2	Deposit Town D							
utcome		Report Type: Periodic		Company Report Number: 5	2417		Age: 19 YR	Can	der: Male
her	PT Depression Nec	Report Source	Product	D	olo.	Manual			. Maie
	Palpitations	Consumer	Accutane	P	ole_	Manufacturer	Route	Dose/Unit	Duration
	Sedation			R	•	Roche	ORAL		

## FDA - Adverse Event Reporting System (APRS). Freedom Of Information (FOI).Report

	meport Type: Periodic		Company Report Numbe	r: 52419		Age: 27 YR	Gen	der: Female
PT	Report Source	Product				-		der. Penale
	Consumer	-					Dose/Unit	Duration
				i.2	Roche	ORAL	80	182 -
ISR Number: 1771523-9	Report Type: Periodic		Company Report Number	- 51520				
PT	Report Source		passy seepote (validate)	1: 32336		Age: 17 YR	Gen	der: Male
Depression Nec				Role	Manufacturer	Route	Dose/Unit	Duration
	Tradat i Torcastonai	Accutane		PS	Roche	ORAL	40	188
ISR Number: 1771557-4	Report Type: Periodic		Company Papart Name L	52502				<del></del>
PT	Denout C		Company Report Numbe	n 32393		Age: 20 YR	Gen	der: Female
Insomnia Nec				Role	Manufacturer	Route	Dose/Unit	Duration
	International			PS	Roche	ORAL	60	23
		Tavist D		C				
ISR Number: 1771573-2	Report Type: Periodic		Company Person Name	E1022				
PT	Damant G		Company Report Number	31277		Age: 25 YR	Gen	der: Female
Asthenia				Role	Manufacturer	Route	Dose/Unit	Duration
Depression Nec	ricatut Professionai	Accutane		PS	Roche	ORAL		44
ISR Number: 1771616-6	Report Type: Periodia							
PT			Company Report Number	: 52078		Age: 20 YR	Gen	der: Male
		Product		Role	Manufacturer	Route	Dose/Unit	Duration
Thinking Abnormal Nec	Health Professional	Асситале		PS	Roche			<u> </u>
ISR Number: 1771657-9	Personal (F) P + 11		<del></del>		· · · · · · · · · · · · · · · · · · ·			
	Report Type: Periodic		Company Report Number	50868		Age: 31 YR	Gen	der: Female
	Report Source	Product	*	Role	Manufacturer	Danta	D	
- mprantons	Health Professional	Accutane		PS				Duration
ISR Number: 1771670-1	D					URAL	20	
	Report Type: Periodic		Company Report Number	: 50875		Age: 15 YR	Gene	der: Male
	Report Source	Product		Role	Manufactures	70		
Pression IASC	Consumer	Accutane						Duration
<del></del>		Prozac			TOTAL CONTRACTOR OF THE PARTY O	UKAL	120	121
ISR Number: 1771675-0	Report Type: Periodic		Comp. 127			· · · · · · · · · · · · · · · · · · ·	<del></del>	133
PT			Company Report Number	52348		Age: 31 YR	Gene	der: Female
Agitation				Role	Manufacturer	Route	Dose/Unit	Duration
Condition Aggravated	rieaun Professional	Accutane		PS	Roche	ORAL		- manufull
	Depression Nec Hepatic Function Abnormal Nos ISR Number: 1771523-9 PT Depression Nec  ISR Number: 1771557-4 PT Insomnia Nec Menstrual Disorder Nos Nervousness ISR Number: 1771573-2 PT Asthenia Depression Nec ISR Number: 1771616-6 PT Amblyopia Nos Thinking Abnormal Nec ISR Number: 1771657-9 PT Palpitations ISR Number: 1771670-1 PT Depression Nec ISR Number: 1771675-0 PT Agitation	PT Report Source  Depression Nec Hepatic Function Abnormal Nos  ISR Number: 1771523-9 Report Type: Periodic  PT Report Source  Depression Nec Health Professional  ISR Number: 1771557-4 Report Type: Periodic  PT Report Source  Health Professional  ISR Number: 1771573-2 Report Type: Periodic  PT Report Source  Health Professional  ISR Number: 1771573-2 Report Type: Periodic  PT Report Source  Asthenia Depression Nec Health Professional  ISR Number: 1771616-6 Report Type: Periodic  PT Report Source  Amblyopia Nos Thinking Abnormal Nec Health Professional  ISR Number: 1771657-9 Report Type: Periodic  PT Report Source  Health Professional  ISR Number: 1771670-1 Report Source  Depression Nec Consumer  ISR Number: 1771675-0 Report Type: Periodic  PT Report Source  Depression Nec Report Type: Periodic  PT Report Source  Health Professional	PT Report Source Consumer Accutane  Product Depression Nec Hepatic Function Abnormal Nos  ISR Number: 1771523-9 Report Type: Periodic  PT Report Source Health Professional Accutane  ISR Number: 1771557-4 Report Source Product  Isr Number: 1771557-4 Report Type: Periodic  PT Report Source Product  Insommia Nec Health Professional Accutane  Menstrual Disorder Nos Nervousness Tavist D  ISR Number: 1771573-2 Report Type: Periodic  PT Report Source Product  Asthenia Health Professional Accutane  Depression Nec Report Type: Periodic  ISR Number: 1771616-6 Report Type: Periodic  PT Report Source Product  Anablyopia Nos Health Professional Accutane  ISR Number: 1771657-9 Report Source Product  Palpitations Report Type: Periodic  PT Report Source Product  Report Source Product  Health Professional Accutane  PT Report Source Product  Report Source Product  Product Report Source Product  PT Report So	PT Report Source Product Depression Nec Health Professional Accutane  ISR Number: 1771523-9 Report Type: Periodic Company Report Number PT Report Source Product Depression Nec Health Professional Accutane  ISR Number: 1771557-4 Report Type: Periodic Company Report Number PT Report Source Product Insomnia Nec Health Professional Accutane Menstrual Disorder Nos Nervousness ISR Number: 1771573-2 Report Type: Periodic Company Report Number PT Report Source Product Asthenia Depression Nec Health Professional Accutane Depression Nec Health Professional Accutane ISR Number: 1771676-6 Report Type: Periodic Company Report Number PT Report Source Product Anablyopia Nos Health Professional Accutane ISR Number: 177167-9 Report Source Product PT Report Source Product PT Report Source Product Anablyopia Nos Health Professional Accutane ISR Number: 1771670-1 Report Type: Periodic Company Report Number PT Report Source Product PT Report Source Product Palpitations Report Source Product Product Company Report Number PT Report Source Product Depression Nec Company Report Number PT Report Source Product Depression Nec Company Report Number PT Report Source Product Depression Nec Company Report Number PT Report Source Product Depression Nec Company Report Number PT Report Source Product Depression Nec Company Report Number	PT Report Source Product Company Report Number: 52419  PT Report Source Product Role  Hepatic Function Abnormal Nos  Report Type: Periodic Company Report Number: 52538  PT Report Source Product Role Depression Nee Health Professional Accutane PS  ISR Number: 1771557-4 Report Type: Periodic Company Report Number: 52593  PT Report Source Product Role Insommia Nee Health Professional Accutane PS  ISR Number: 1771573-2 Report Type: Periodic Company Report Number: 51277  PT Report Source Product Role Asthenia Health Professional Accutane PS  ISR Number: 1771573-2 Report Type: Periodic PS  ISR Number: 1771616-6 Report Type: Periodic Company Report Number: 51277  PT Report Source Product Role Amblyopia Nos Health Professional Accutane PS  ISR Number: 1771657-9 Report Type: Periodic Company Report Number: 52078  PT Report Source Product Role Amblyopia Nos Health Professional Accutane PS  ISR Number: 1771657-9 Report Type: Periodic Company Report Number: 50868  PT Report Source Product Role Palpitations Report Type: Periodic Company Report Number: 50875  PT Report Source Product Role Palpitations Report Type: Periodic Company Report Number: 50875  PT Report Source Product Role Palpitations Report Type: Periodic Company Report Number: 50875  PT Report Source Product Role Palpitations Report Type: Periodic Company Report Number: 50875  PT Report Source Product Role Product Role Product Role Product Role Product Role Role Product Role Role Role Product Role Role Role Role Product Role Role Role Role Role Role Role Role	PT Report Source Product Role Manufacturer  Depression Nee Health Professional Accutane Product Role Manufacturer  PT Report Source Product Role Manufacturer  Depression Nee Health Professional Accutane Product Role Manufacturer  Depression Nee Health Professional Accutane Product Role Manufacturer  PT Report Source Product Role Manufacturer  Depression Nee Health Professional Accutane Product Role Manufacturer  ISR Number: 1771557-4 Report Source Product Role Manufacturer  ISR Number: 1771573-2 Report Source Product Role Manufacturer  ISR Number: 1771573-2 Report Source Product Role Roche  ISR Number: 1771573-2 Report Source Product Role Manufacturer  Asthenia Depression Nee Health Professional Accutane Product Role Manufacturer  Asthenia Depression Nee Health Professional Accutane Product Role Manufacturer  ISR Number: 1771616-6 Report Source Product Role Manufacturer  Amblyopia Nos Health Professional Accutane Product Role Manufacturer  PT Report Source Product Role Manufacturer  Product Role Manufacturer  Accutane Product Role Manufacturer  Accutane Product Role Manufacturer  PRODUCT ROLE ROLE MANUfacturer  PRODUCT ROLE ROLE MANUfacturer  PRODUCT ROLE ROLE MANUfacturer  PRODUCT ROLE ROLE MANUfacturer  Accutane Role Manufacturer  PRODUCT ROLE ROLE ROLE ROLE MANUfacturer  PRODUCT ROLE ROLE ROLE ROLE MANUfacturer  PRODUCT ROLE ROLE ROLE ROLE ROLE MANUfacturer  PRODUCT ROLE ROLE ROLE ROLE ROLE MANUfacturer  PRODUCT ROLE ROLE ROLE ROLE ROLE ROLE ROLE MANUfacturer  PRODUCT ROLE ROLE ROLE ROLE ROLE ROLE ROLE ROLE	PT	PT   Report Source   Product   Report Number: 52419   Report Source   Product   Report Number: 177153-2   Report Type: Periodic   Company Report Number: 52538   Report Type: Periodic   Report Number: 52578   Report Type: Periodic   Report Number: 52578   Report Type: Periodic   Report Type: Periodic   Report Number: 52578   Report Type: Periodic   Report Type: Periodic   Report Number: 52578   Report Type: Periodic   Report Type: Periodic   Report Number: 52578   Report Type: Periodic   Report Type: Periodic   Report Number: 52578   Report Type: Periodic   Report Type: Periodic   Report Number: 52578   Report Number: 52578   Report Type: Periodic   Report Number: 52578   Report Type: Periodic   Report Number: 52578   Report

			readon	e Event Report Of Information	(1)	Report			
Date: 06/13/1996	ISR Number: 1771696-8	Report Type: Periodic		Company Report Numb	er: 50978		Age: 33 YR	g.	
Ontcome	PT	Report Source	Product				14ge: 35 IK	Ge	nder: Female
Other	Dry Skin	Consumer			Role	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos Headache Nos	<u> </u>	Accutane		PS	Roche	ORAL	40	32
Date: 06/13/1996	ISR Number: 1771714-7	Report Type: Periodic		Company Report Number	51000				···
Outcome	PT	Danast Carre		· ····F-ily stepost (vulips	er: 51000		Age: 64 YR	Ge	nder: Male
Other	Difficulty In Micturition	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Epistaxis	Consumer	Accutane		PS	Roche	ORAL	40	121
	Hyperglycaemia Nos		Lopressor		С			70	121
	Impotence			*					
Date: 06/13/1996	ISR Number: 1771734-2	Report Type: Periodic		Command D		<del> </del>	<del></del>		
Outcome	PT			Company Report Number	er: 60241		Age: 32 YR	Ger	nder: Female
Other	Emotional Disturbance Nos	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Hyperkinetic Syndrome	Consumer	Accutane		PS	Roche	ORAL		
	Joint Disorder Nos						OKAL	30	416
	Rhinitis Nos								
Date: 06/13/1996	ISR Number: 1771741-X	Report Type: Periodic		<del></del>					
Outcome	PT	acepore Type: Penodic		Company Report Numbe	r: 60330		Age: 38 YR	Ger	nder: Female
Other	Acne Nos	Report Source	Product		Role	M * .	_		Tanac
	Breast Enlargement	Health Professional	Accutane		PS	Manufacturer	Route	Dose/Unit	Duration
	Emotional Disturbance Nos				19	. Roche	ORAL	80	194
	Myalgia								
ate: 06/13/1996	ISR Number: 1771748-2								
	1//1/48-2	Report Type: Periodic		Company Report Number	: 60066		A 00 YED		
Outcome	PT	Report Source	Decident				Age: 22 YR	Gen	nder: Female
Other	Agitation	Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Depression Nec	~~ diomited	Accutane		PS	Roche	ORAL	40	433
ate: 06/13/1996	ISR Number: 1771752-4	Report Type: Periodic		<del></del>		······································			
utcome	Dri	amport appe: Periodic		Company Report Number	r: 58876		Age:	Ger	ıder: Female
ther	PT Cough	Report Source	Product		Role	Manusc	_		I CHALC
	Palpitations	Consumer	Accutane		PS	Manufacturer	Route	Dose/Unit	Duration
te: 06/13/1996	ISR Number: 1771753-6				гэ	Roche	ORAL		
		Report Type: Periodic		Company Report Number	: 58905		Age: 17 YR		
utcome	PT	Report Source	Product				Age: 1/YK	Gen	ider: Male
her	Migraine Nos	Health Professional			Role	Manufacturer	Route	Dose/Unit	Duration
	Sleep Disorder Nos		Accutane		PS	Roche			

			region	e Event Reporting Of Information (F		Remot			
Date: 06/13/1996	ISR Number: 1771754-8	Report Type: Periodic							
Outcome	PT	· ·		Company Report Number: 5	8890		Age:	Ger	ıder: Male
Other	Libido Decreased	Report Source	Product	Re	ole	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Accutane	PS	:	Roche	ORAL	Dost Care	Duration
Date: 06/13/1996	ISR Number: 1771783-4	Report Type: Periodic		Company Report Number: 5	9009		Age: 14 YR		
Outcome	PT	Report Source	Product				Age. 14 1 K	Gen	ıder: Male
Other	Emotional Disturbance Nos	Health Professional			ole_	Manufacturer	Route	Dose/Unit	Duration
Det DENGMONE			Accutane	PS	;	Roche	ORAL	80	
Date: 06/13/1996	ISR Number: 1771785-8	Report Type: Periodic		Company Report Number: 60	3323	· · · · · · · · · · · · · · · · · · ·	4		
Outcome	PT	Report Source	D . 1 .	. ,			Age: 20 YR	Gen	ider: Female
Other	Depression Nec	Health Professional	Product	Ro		Manufacturer	Route	Dose/Unit	Duration
D. 4. 0444		Treatm 1 Toressional	Accutane	PS		Roche	ORAL		
Date: 06/13/1996	ISR Number: 1772242-5	Report Type: Periodic		Company Report Number: 58	2650				·
Outcome	PT	Report Source		company report runner: 38	800		Age: 25 YR	Gen	ider: Female
Other	Amnesia Nec	Health Professional	Product	Ro	le_	Manufacturer	Route	Dose/Unit	Duration
		ricadh i folessionar	Accutane	PS		Roche	ORAL	50	51
Date: 06/13/1996	Tonay		Demalen	c					••
	ISR Number: 1772247-4	Report Type: Periodic		Company Report Number: 58	651	·	Age: 20 YR		
Outcome	<u>PT</u>	Report Source	Product				Age. 20 IR	Gen	der: Female
Other	Asthenia	Health Professional	Accutane	Ro	_	Manufacturer	Route	Dose/Unit	Duration
	Insomnia Nec		Accurate	PS		Roche	ORAL	40	
Date: 06/13/1996	ISR Number: 1772470-9	Report Type: Periodic		Company Report Number: 60					
Outcome	PT			Company Report Number: 60	819		Age: 28 YR	Gen	der: Female
Other	Amnesia Nec	Report Source Consumer	Product	Rol	le_	Manufacturer	Route	Dose/Unit	Duration
	Rectal Bleeding	Consumer	Accutane	PS		Roche	ORAL	1	184
	Tremor Nec							•	104
	Vitreous Disorder Nos								
late: 06/13/1996	ISR Number: 1772487-4	Report Type: Periodic		Company Decad No.					
Outcome	PT			Company Report Number: 61	U36		Age: 28 YR	Gen	der: Female
Other	Depression Nec	Report Source	Product	Rol	e	Manufacturer	Route	Dose/Unit	Duration
	Headache Nos	Consumer	Accutane	PS		Roche	ORAL	80	111
	Pain Nos						S.O.L.	00	111
	Paraesthesia Nec								

		FDA		Tvem Reporti					
			recion	Of Information		tem Auks Report			
Date: 06/13/1996	ISR Number: 1772537-5	Report Type: Periodic		Company Report Numb	er: 60875		Age: 17 YR		
Outcome	PT	Report Source	Product	•			21gc. 17 fR	Ger	nder: Female
Other	Dry Eye Nec Emotional Disturbance Nos Refractive Errors Nos	Health Professional	Accutane		Role PS	Manufacturer Roche	Route ORAL	Dose/Unit 60	Duration 61
Date: 06/13/1996	ISR Number: 1772591-0	Report Type: Periodic							
Outcome	· PT	stoport Type: Periodic		Company Report Number	er: 59965		Age: 52 YR	Gen	ider: Male
Other	Amnesia Nec	Report Source	Product		Role	Manufacturer	Route	December 1	<b>.</b>
	- Indicate (100	Health Professional	Accutane Tetracycline		PS	Roche	ORAL	Dose/Unit 20	Duration 353
Date: 06/13/1996	ISR Number: 1772999-3	Report Type: Periodic	- Totaleyenine	Company Report Numbe	C 45202	<del></del>			
Outcome	PT	Report Source		Company Report Million	ar: 43203		Age: 14 YR	Gen	ider: Male
Other	Asthenia	Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Infection Nos		Accutane Kenalog		PS	Roche	ORAL	60	82
	Major Depressive Disorder Nos Myalgia		Amoxil		C C				
ate: 06/13/1996	ISR Number: 1773008-2	Report Type: Periodic		Company Report Numbe		-			· · · · · · · · · · · · · · · · · · ·
Outcome	_ <b>P</b> Ť.	D		Company Report Numbe	r: 30941		Age: 35 YR	Gen	der: Female
Other	Blindness Night	Report Source Consumer	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Cyst Nos	Consumer	Accutane		PS	Roche	ORAL	80	92
	Depression Nec		Micronor		C				72
ate: 06/13/1996	Menstrual Disorder Nos		Synthroid		C :				
utcome	ISR Number: 1773013-6	Report Type: Periodic		Company Report Number	r: 50280		Age: 30 YR	Gen	der: Female
ther	PT Amblyopia Nos	Report Source	Product		Role	Manufacturer	Route		
	Depression Nec	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration
	Hypertonia						ORAL		246
	Peripheral Neuropathy Nec								
te: 06/13/1996	ISR Number: 1773022-7	Report Type: Periodic		Company Report Number	: 50455	<del></del>	A 24 XID		
stcome	PT	Report Source	Product				Age: 31 YR	Gen	der: Female
her	Agitation	Consumer	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Anxiety Nec Tremor Nec		Xanax		PS	Roche	ORAL	60	
	TICHIOT INEC		Value		C .				

		Consumer	Accutane		PS			2 Jack Chill	Duration
outcome Ther	PT Insomnia Nec	Report Source	Product		Role	Manufacturer	Route	Gene Dose/Unit	1 Chiaic
ite: 06/13/1996	ISR Number: 1774780-8	Report Type: Periodic		Company Report Numbe	r: 54534	<del></del>	Age: 48 YR		
	Impotence	Health Professional	Accutane		PS	Roche	ORAL	DOSC OBIL	Duration
ther	PT Abnormal Dreams	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	
utcome	ISR Number: 1774745-6	Report Type: Periodic	-	Company Report Number	r: 54452		Age: 17 YR	Gen	der: Male
ate: 06/13/1996	Urinary Frequency								
	Ejaculation Disorder Nos Faccal Abnormality Nos	- Activi i Tojessional	Accutane		PS	Roche	ORAL	80	61
ther	Depression Nec	Report Source Health Professional	Product	*	Role	Manufacturer	Route	Dose/Unit	Duration
ate: 06/13/1996 Outcome	ISR Number: 1774528-7	Report Type: Periodic		Company Report Number	er: 53568		Age: 17 YR	Gen	der: Male
		Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit	Duration
Outcome Other	PT Depression Nec	Report Source	Product		Role	Manufacturer			der: Female
Pate: 06/13/1996	ISR Number: 1774522-6	Report Type: Periodic		Company Report Numb	er: 53284		Age: 25 YR		
			Deltasone		C C				
		1 Ioutil 1 Totessional	Accutane Darvocet-N		PS	Roche	ORAL	40	
Other	Emotional Disturbance Nos	Report Source Health Professional	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Outcome	PT	Report Type: Periodic		Company Report Numb	er: 53405		Age: 20 YR	Gen	der: Male
Date: 06/13/1996	Emotional Disturbance Nos  ISR Number: 1774519-6								
	Dyspepsia				•	20000	ORAL		187
Other	Alopecia Dry Eye Nec	Consumer	Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
Outcome	PT	Report Source	Product	Company Report Numb			Age: 19 YR	Gen	ider: Male
Date: 06/13/1996	ISR Number: 1774506-8	Report Type: Periodic		Common Day (5)		TOTALIC .	ORAL,	40	146
Other	Hostility	Health Professional	Product Accutane		Role PS	Manufacturer Roche	Route	Dose/Unit	Duration
Outcome	PT	Report Source		Company Report Numb	er: 59666		Age: 18 YR	Ger	ider: Male
Date: 06/13/1996	ISR Number: 1774354-9	Report Type: Periodic							

	23.24	FDA	Arlvers Tenton	e Event Reporti Of Information		dem (ARRS) Report				
Date: 06/13/1996 Outcome	PT PT	Report Type: Periodic  Report Source	Product	Company Report Number			Age: 24 YR	Ge	nder: Male	
Other	Thinking Abnormal Nec	Consumer	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration	
			Nytol		rs C	Roche	ORAL	80		
Date: 06/13/1996	ISR Number: 1778184-3	Report Type: Periodic		Company Report Number		<del>· · · · · · · · · · · · · · · · · · · </del>	Age: 39 YR			
Outcome	PT	Report Source	Product				Age: . 39 IK	Ger	nder: Fcmale	
Other	Breast Pain Depression Nec	Consumer	Accutane		Role PS	Manufacturer	Route	Dose/Unit	Duration	
	Epistaxis		Prednisone		C PS	Roche	ORAL	60	123	
	Menstrual Disorder Nos				C	•			1 .	
Date: 06/13/1996 Outcome	ISR Number: 1778216-2	Report Type: Periodic		Company Report Numbe	r: 56403		Age: 37 YR	Ger	nder: Female	
Other	Appetite Increased	Report Source	Product		Role	Manufacturer	Route	D. #7.4		
	Depression Nec	Consumer	Accutane		PS	Roche	ORAL	Dose/Unit	Duration	
	Emotional Disturbance Nos Flatulence						OKAL .	40		
Date: 06/13/1996	ISR Number: 1778231-9	Report Type: Periodic		Comment			· · · · · ·			
Outcome	PT			Company Report Numbe	r: 56187		Age: 18 YR	Gen	ıder: Male	
Other	Amblyopia Nos	Report Source Consumer	Product	<del></del>	Role	Manufacturer	Route	Dose/Unit	Duration	
	Depression Nec	Consumer	Accutane		PS	Roche	ORAL	80	35	
	Dry Skin Emotional Disturbance Nos									
Date: 06/13/1996										
	ISR Number: 1778308-8	Report Type: Periodic		Company Report Number	r: 55937		A 05370			
Outcome	PT	Report Source	Product				Age: 35 YR	Gen	ider: Female	
Other	Emotional Disturbance Nos	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
	Hypersensitivity Nos Palpitations		. Iccurant		PS	Roche	ORAL	40	9	
-	Rectal Bleeding									
ate: 06/13/1996	ISR Number: 1778442-2	Report Type: Periodic		Company Report Number	- 56812					
Outcome	PT	Report Source	Dandard		. 50012		Age: 25 YR	Gen	der: Female	
ther	Libido Decreased	Health Professional	Product Accutane		Role	Manufacturer	Route	Dose/Unit	Duration	
<del></del>			Accutane		PS	Roche	ORAL			

		TUA		Exent Reports		Britis (Alli Res)			
			regions	M Information	0000	Report			
Date: 06/13/1996	ISR Number: 1778533-6	Report Type: Periodic		Company Report Number	r: 53042		Age: 40 YR	Ger	der: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	Route	D #7.4	
Other	Nervousness	Health Professional	Accutane		PS	Roche	ORAL	Dose/Unit 20	Duration 13
Date: 09/18/1996	ISR Number: 1795768-7	Report Type: Expedited	(15-Day)	Company Report Numbe	er: 67928		Age: 25 YR	Gen	ider: Male
Outcome	_ PT	Report Source	Product	•			•	Ga	mer: Mase
Hospitalization -	Confusion	Health Professional	Accutane		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged Disability	Depression Nec		ricciant		PS	Roche	ORAL	80	124
1/1800ШКУ	Emotional Disturbance Nos Thinking Abnormal Nec								
Date: 09/10/1996	ISR Number: 1801886-7	Report Type: Expedited	(15-Day)	Company Report Number	r: 67453		Age: 28 YR	Ger	ıder: Female
Outcome	PT	Report Source	Product		Role	Manufacturer	D		
Hospitalization -	Aphasia	Health Professional	Accutane		PS	Roche	Route	Dose/Unit	Duration
Initial or Prolonged	Confusion				rs	Rocne	ORAL	80	5
	Headache Nos Vomiting Nos								
Date: 10/01/1996	ISR Number: 1820874-8	Report Type: Expedited	(15-Day)	Company Report Numbe	₩ 68681		A 1CVD		
Outcome	PT	Report Source		,,			Age: 16 YR	Gen	der: Female
Hospitalization -	Condition Aggravated	Foreign	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Major Depressive Disorder Nos	Health Professional	Roaccutane	*	PS	Roche	ORAL	20	
	Suicide Attempt	Ticalul I Totessioliai	Diane		C				
Date: 11/20/1996	ISR Number: 1841822-0	Report Type: Expedited	(15-Day)	Company Report Numbe	r: 71977		Age: 15 YR	Gen	der: Male
Outcome	PT	Report Source	Product		Role	Manufacture			
Hospitalization -	Dysarthria	Foreign	Roaccutane		PS	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Headache Nos	Health Professional			1.2	Roche	ORAL	35	9
	Paraesthesia Nec Peripheral Neuropathy Nec								
Date: 11/12/1996	ISR Number: 1847288-9	Report Type: Expedited (	15-Day)	Company Report Numbe	- 68760	<del> </del>	47.77		-
Outcome	PT	_	•	Land webare 14mine	00700		Age: 17 YR	Gen	der: Male
Other	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Suicide Attempt	Foreign	Roaccutane		PS	Roche	ORAL	40	86
	Thinking Abnormal Nec								

				e Event Report		tem (AERS)			
				Of hiformation		Report			
Date: 11/12/1996	ISR Number: 1847313-5	Report Type: Expedited	(15-Day)	Company Report Num	ber: 68764		Age: 18 YR	C-	nder: Male
Outcome	PT	Report Source	Product				10 IK		nder: Male
Other	Psychotic Disorder Nos	Foreign	Roaccutane		Role	Manufacturer	Route	Dose/Unit	Duration
Date: 12/09/1996	Top av	<del></del>		<u></u>	PS	Roche	ORAL	60	87
_	ISR Number: 1847904-1	Report Type: Expedited	(15-Day)	Company Report Num	ber: 72443		Age: 20 YR	Ca	nder: Male
Outcome	PT	Report Source	Product				12ge 20 IK	Ge	nder: Male
Hospitalization - Initial or Prolonged	Depression Nec	Foreign	Roaccutane		Role	Manufacturer	Route	Dose/Unit	Duration
	Suicide Attempt	Health Professional	Monteumie	•	PS	Roche	ORAL		
Date: 11/07/1996	ISR Number: 1848747-5	Report Type: Expedited	(15-Day)	Company					
Outcome	PT		- Day)	Company Report Numl	ber: 71105		Age: 17 YR	Ge	nder: Male
Hospitalization -	Extrapyramidal Disorder Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
Initial or Prolonged	Insomnia Nec	Foreign	Roaccutane		PS	Roche	ORAL		
	Mydriasis	Health Professional	Vitamin C		C				
	Pain Nos		Acetaminop	hen	С				
Date: 11/12/1996	ISR Number: 1849153-X	Report Type: Expedited	15-Day)	Company Report Numb	21470	<del></del>	<del></del>		
Outcome	PT	Report Source	-	Company Report Numi	er: /14/0		Age: 26 YR	Ge	nder: Male
Death	Suicide Attempt	Foreign	Product		Role	Manufacturer	Route	Dose/Unit	Duration
		Health Professional	Roaccutane		PS	Roche	ORAL	100	148
ate: 12/10/1996	TOTAL	Treatur Froressional	Prednisone		С				64 .
	ISR Number: 1849258-3	Report Type: Expedited (	15-Day)	Company Report Numb	er: 72895		Age:		
Outcome	PT	Report Source	Product				age.	Ge	nder: Female
Disability	Amblyopia Nos	Consumer	Accutane	<del></del>	Role	Manufacturer	Route	Dose/Unit	Duration
	Ataxia Nec Thinking Abnormal Nec		Phenergan		PS	Roche	ORAL	80	3
	Tinnitus Abnormal Nec		Prozac		. C				
			Lortab.		C				
·			Baclofen		С				
ate: 12/26/1996	ISR Number: 1869957-7	Report Type: Expedited (		Company Report Numb	C er: 73516	<del></del>	A 4677D		<del> </del>
utcome	PT	Report Source	Dandard				Age: 15 YR	Ger	ıder: Male
ospitalization -	Aphasia	Foreign	Product		Role	Manufacturer	Route	Dose/Unit	Duration
nitial or Prolonged	Laboratory Test Abnormal Nos	Health Professional	Roaccutane		PS	Roche	ORAL	35	10
	Migraine Nos								
	Peripheral Neuropathy Nec								

		FDA	A TUBER	Event Reports					
			Frederi	Of Information		Report			
Date: 03/11/1997 Outcome	ISR Number: 1891089-2	Report Type: Expeditor	(15-Day)	Company Report Number	r: 76693		Age: 15 YR	Ge	nder: Female
Other	PT Depression Nec	Report Source	Product		Role	Manufacturer			
Olice	Suicide Attempt	Poreign	Roaccutane		PS	Roche	Route	Dose/Unit	Duration
		Health Professional			10	Roche	ORAL		367
Date: 01/21/1997	ISR Number: 1896111-5	Report Type: Expedited	(15-Day)	Community D. A.N. D.					
Outcome	PT		(** 15 <b>4</b> )	Company Report Numbe	r: 63416		Age: 42 YR	Ge	nder: Female
Other	Depression Nec	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
	Myalgia	Consumer	Accutane		PS	Roche	ORAL.	10	
	Peripheral Neuropathy Nec		Librium		SS	Roche	OKAL,	10	71
	Rhinitis Nos		Norpramin		С				
Date: 01/24/1997	ISR Number: 1899346-0	Report Type: Expedited	(IE D)			·	·		
Outcome	PT		(13-13ay)	Company Report Number	r: 74849		Age:	Ger	nder: Unknown
Congenital Anomaly	Blindness Nec	Report Source	Product		Role	Manufacturer	Route	D #7-#	
,	Congenital Abnormality Nos	Foreign	Roaccutane		PS	Roche	TRANSPLA	Dose/Unit	Duration
	Congenital Central Nervous			-			CENTAL		14
	System Anomaly Nos Mental Retardation Severity								
	Unspecified Unspecified	•							
late: 02/11/1997	ISR Number: 1906164-3	Report Type: Periodic							
Outcome	PT	Report Type: Periodic		Company Report Number: 896290007N		007N	Age: 32 YR	Ger	nder: Female
Hospitalization -	Acne Nos	Report Source	Product		Role	Manufacturer	<b>-</b> .		
nitial or Prolonged	Benign Intracranial	Consumer	Norplant		PS	Wyeth	Route	Dose/Unit	Duration
Other	Hypertension				10	** your	SUBCUTAN EOUS		
	Depression Nec		Accutane		SS	Roche	ORAL		426
ot 05 00 400=	Weight Increased	<del> </del>							
ate: 05/20/1997	ISR Number: 1924247-9	Report Type: Expedited (	15-Day)	Company Report Number	90052	<del></del>	<del></del>		
Outcome	PT		•		7 60933		Age: 13 YR	Gen	nder: Female
lospitalization -	Suicide Attempt	Report Source	Product		Role	Manufacturer	Route	Dose/Unit	Duration
nitial or Prolonged		_	Accutane		PS	Roche	ORAL	40	14
ate: 04/28/1997	ISR Number: 1924269-8	Report Type: Expedited (	IF D						14
utcome	PT		13-1)ay)	Company Report Number	80102		Age: 21 YR	Gen	der: Male
ther	Paranoia	Report Source	Product		Role	Manufacturer	<b>.</b>		Marc
	Psychotic Disorder Nos	Foreign	Roaccutane		PS	Roche	Route	Dose/Unit	Duration
						ACCIE	ORAL		62