

Criteria Sheet

Report Criteria

Report Name: S3A001
Report Version: 1
Description: S3A001
Product Selection: timolol maleate (Ingredient)
Study Selection: None
Event Selection: None
Data Source: Argus
Date Range Type: Case Receipt Date
Exclude Non-Valid Cases: Yes
Exclude Follow-Up: No
Limit to Suspect Product: No
Limit to Primary Path: No
Include Medically Confirmed Cases Only: No
Include Locked Cases Only: Yes
Limit to Case Series: None
Include Non-Significant Followup Cases: No
Include All Study Drugs Cases: No
Report Owner: bhagya (bhagya)
Run Date and Time: 17-Jul-2020 08:06:20 AM UTC

Section Title	Template Name	Query	Parameters	Date Range	Evaluate Case Data as of	Query Level	Case Count
S3A001	Case Line Listing (Study)	None	None	01-Dec-1999 To 31- Dec-1999	17-Jul-2020	Case	98

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
00010640	17-Dec-1999		Spontaneous	0950	timolol maleate (S)		General symptom	-	Unknown
Product Name (Drug Type) 1) timolol maleate(S) - All									Not Assessed
00011114	22-Dec-1999	0950	34061 Report From Study	0950	timolol maleate (S)	23-NOV-1999	Hepatocellular carcinoma	MS	Not Related
			34061 Clinical Trial						Not Related
Product Name (Drug Type) 1) timolol maleate(S) - All									
00011117	22-Dec-1999	0950	Report From Study	0950	timolol maleate (S)	30-OCT-2000	Hepatocellular carcinoma	D	Not Related
			Clinical Trial						Not Related
						02-NOV-1999	Hepatocellular carcinoma	MS	Not Related
Product Name (Drug Type) 1) timolol maleate(S) - All									Not Related
00012056	29-Dec-1999	0950	24003 Report From Study	0950	timolol maleate (S)	27-APR-1999	Meniscus injury -		Not Related
			24003 Clinical Trial						Not Related
					acetaminophen (C)	27-APR-1999	Meniscus injury -		
Product Name (Drug Type) 1) timolol maleate(S) - All 2) acetaminophen(C)									
00013502	30-Dec-1999		Spontaneous	0950E	timolol maleate (+) pilocarpine hydrochloride (S)	15-JUL-1999	Atrioventricular block second degree	H, LT	Related
									Related
						12-JUL-1999	Hypoglycaemia	MS, H	Unknown
				1506	methotrexate (C)	15-JUL-1999	Atrioventricular block second	H, LT	Unknown

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							degree		
						12-JUL-1999	Hypoglycaemia	MS, H	
				9039	folic acid (C)	15-JUL-1999	Atrioventricular block second degree	H, LT	
						12-JUL-1999	Hypoglycaemia	MS, H	
					acetaminophen (C)	15-JUL-1999	Atrioventricular block second degree	H, LT	
						12-JUL-1999	Hypoglycaemia	MS, H	
					codeine phosphate (C)	15-JUL-1999	Atrioventricular block second degree	H, LT	
						12-JUL-1999	Hypoglycaemia	MS, H	
					ISOPHANE INSULIN (C)	15-JUL-1999	Atrioventricular block second degree	H, LT	
						12-JUL-1999	Hypoglycaemia	MS, H	
					insulin (C)	15-JUL-1999	Atrioventricular block second degree	H, LT	
						12-JUL-1999	Hypoglycaemia	MS, H	

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					IRBESARTAN (C)	15-JUL-1999	Atrioventricular block second degree	H, LT
						12-JUL-1999	Hypoglycaemia	MS, H
				0421	enalapril maleate (C)	15-JUL-1999	Atrioventricular block second degree	H, LT
						12-JUL-1999	Hypoglycaemia	MS, H
				0950E	timolol maleate (+) pilocarpine hydrochloride (C)	15-JUL-1999	Atrioventricular block second degree	H, LT
						12-JUL-1999	Hypoglycaemia	MS, H
						15-JUL-1999	Atrioventricular block second degree	H, LT
						12-JUL-1999	Hypoglycaemia	MS, H

Product Name (Drug Type) 1) timolol maleate (+) pilocarpine hydrochloride(S)
- All 2) methotrexate(C)
3) folic acid(C)
4) acetaminophen(C)
5) codeine phosphate(C)
6) ISOPHANE INSULIN(C)
7) insulin(C)
8) IRBESARTAN(C)
9) enalapril maleate(C)
10) timolol maleate (+) pilocarpine hydrochloride(C)

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11) timolol maleate (+) pilocarpine hydrochloride(C)									
00015514	14-Dec-1999		Spontaneous	0950	timolol maleate (S)		Myalgia	-	Related
Product Name (Drug Type) 1) timolol maleate(S) - All									Unknown
00020382	28-Dec-1999	0950	Report From Study Clinical Trial	0950	timolol maleate (S)	06-DEC-1999	Chest pain	MS, H	Related
Product Name (Drug Type) 1) timolol maleate(S) - All									Related
00030209	17-Dec-1999		Spontaneous	0950	timolol maleate (S)	13-DEC-1999	Vision blurred	-	Unknown
									Not Assessed
						13-DEC-1999	General symptom	-	Unknown
Product Name (Drug Type) 1) timolol maleate(S) - All									Not Assessed
00040894	08-Dec-1999		Spontaneous	0950	timolol maleate (S)	25-NOV-1999	Blood pressure increased	MS, H	Related
									Related
						25-NOV-1999	Ventricular arrhythmia	MS, H	Related
									Related
						25-NOV-1999	Blood pressure increased	MS, H	
						25-NOV-1999	Ventricular arrhythmia	MS, H	
						epinephrine (S)	25-NOV-1999	Blood pressure increased	MS, H

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						25-NOV-1999	Ventricular arrhythmia	MS, H	
					unoprostone isopropyl ester (C)	25-NOV-1999	Blood pressure increased	MS, H	
						25-NOV-1999	Ventricular arrhythmia	MS, H	
					meperidine hydrochloride (C)	25-NOV-1999	Blood pressure increased	MS, H	
						25-NOV-1999	Ventricular arrhythmia	MS, H	
					atropine sulfate (C)	25-NOV-1999	Blood pressure increased	MS, H	
						25-NOV-1999	Ventricular arrhythmia	MS, H	
					thiamylal (C)	25-NOV-1999	Blood pressure increased	MS, H	
						25-NOV-1999	Ventricular arrhythmia	MS, H	
					vecuronium bromide (C)	25-NOV-1999	Blood pressure increased	MS, H	
						25-NOV-1999	Ventricular arrhythmia	MS, H	

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					midazolam (C)	25-NOV-1999	Blood pressure increased	MS, H	
						25-NOV-1999	Ventricular arrhythmia	MS, H	
					sevoflurane (C)	25-NOV-1999	Blood pressure increased	MS, H	
						25-NOV-1999	Ventricular arrhythmia	MS, H	
					tegafur (C)	25-NOV-1999	Blood pressure increased	MS, H	
						25-NOV-1999	Ventricular arrhythmia	MS, H	
					uracil mustard (C)	25-NOV-1999	Blood pressure increased	MS, H	
						25-NOV-1999	Ventricular arrhythmia	MS, H	

Product Name (Drug Type)

- All

- 1) timolol maleate(S)
- 2) lidocaine(C)
- 3) epinephrine(S)
- 4) unoprostone isopropyl ester(C)
- 5) meperidine hydrochloride(C)
- 6) atropine sulfate(C)
- 7) thiamylal(C)
- 8) vecuronium bromide(C)
- 9) midazolam(C)
- 10) sevoflurane(C)
- 11) tegafur(C)

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12) uracil mustard(C)									
95091740	28-Sep-1995		Literature Marketed	0507	dorzolamide hydrochloride (S)	24-AUG-1995	Corneal defect	DIS	Related
									Related
					pilocarpine (C)	24-AUG-1995	Corneal defect	DIS	
				0950	timolol maleate (C)	24-AUG-1995	Corneal defect	DIS	
					methazolamide (S)	24-AUG-1995	Corneal defect	DIS	
					fluorometholone (C)	24-AUG-1995	Corneal defect	DIS	
Product Name (Drug Type) - All 1) dorzolamide hydrochloride(S) 2) pilocarpine(C) 3) timolol maleate(C) 4) methazolamide(S) 5) fluorometholone(C)									
95100389	28-Sep-1995		Literature Marketed	0507	dorzolamide hydrochloride (S)	05-SEP-1995	Corneal decompensatio n	DIS	Related
									Related
				0950	timolol maleate (C)	05-SEP-1995	Corneal decompensatio n	DIS	
					methazolamide (S)	05-SEP-1995	Corneal decompensatio n	DIS	
Product Name (Drug Type) - All 1) dorzolamide hydrochloride(S) 2) timolol maleate(C)									

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3) methazolamide(S)									
95121003	05-Dec-1995		Literature Marketed	0507	dorzolamide hydrochloride (S)	13-SEP-1995	Corneal defect	DIS	Related
				0950	timolol maleate (C)	13-SEP-1995	Corneal defect	DIS	Related
Product Name (Drug Type) 1) dorzolamide hydrochloride(S) - All 2) timolol maleate(C)									
97062383	15-Jul-1997		Spontaneous	0217	alendronate sodium (S)	MAY-1999	Musculoskeletal - pain		Unknown
						JUN-2007	Inappropriate schedule of product administration	-	Unknown
						JUL-1997	Alopecia	-	Not Related
						01-JUN-1997	Hirsutism	-	Unknown
						MAY-1999	Pain in extremity	-	Not Assessed
						MAY-1999	Pelvic pain	-	Unknown
						MAY-1999	Back pain	-	Unknown
				0507A	dorzolamide hydrochloride (+) timolol maleate (C)	MAY-1999	Musculoskeletal - pain		Unknown

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					JUN-2007	Inappropriate schedule of product administration	-
					JUL-1997	Alopecia	-
					01-JUN-1997	Hirsutism	-
					MAY-1999	Pain in extremity	-
					MAY-1999	Pelvic pain	-
					MAY-1999	Back pain	-
				L-thyroxine (C)	MAY-1999	Musculoskeletal pain	-
					JUN-2007	Inappropriate schedule of product administration	-
					JUL-1997	Alopecia	-
					01-JUN-1997	Hirsutism	-
					MAY-1999	Pain in extremity	-
					MAY-1999	Pelvic pain	-

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					MAY-1999	Back pain	-	
				ibuprofen (C)	MAY-1999	Musculoskeletal pain	-	
					JUN-2007	Inappropriate schedule of product administration	-	
					JUL-1997	Alopecia	-	
					01-JUN-1997	Hirsutism	-	
					MAY-1999	Pain in extremity	-	
					MAY-1999	Pelvic pain	-	
					MAY-1999	Back pain	-	
				docusate sodium (C)	MAY-1999	Musculoskeletal pain	-	
					JUN-2007	Inappropriate schedule of product administration	-	
					JUL-1997	Alopecia	-	
					01-JUN-1997	Hirsutism	-	

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						MAY-1999	Pain in extremity	-	
						MAY-1999	Pelvic pain	-	
						MAY-1999	Back pain	-	
					betaxolol hydrochloride (C)	MAY-1999	Musculoskeletal pain	-	
						JUN-2007	Inappropriate schedule of product administration	-	
						JUL-1997	Alopecia	-	
						01-JUN-1997	Hirsutism	-	
						MAY-1999	Pain in extremity	-	
						MAY-1999	Pelvic pain	-	
						MAY-1999	Back pain	-	
Product Name (Drug Type) 1) alendronate sodium(S) - All 2) dorzolamide hydrochloride (+) timolol maleate(C) 3) L-thyroxine(C) 4) ibuprofen(C) 5) docusate sodium(C) 6) betaxolol hydrochloride(C)									

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98010833	27-Nov-1997	0950	34037	0950	timolol maleate (S)	17-NOV-1997	Hepatocellular carcinoma	H	Not Related
			34037						Not Related
						10-SEP-1999	Hepatic failure	D	Not Related
									Not Related
						22-MAR-1999	Hepatocellular carcinoma	H	Not Related
									Not Related
						22-MAR-1999	Nausea	H	Not Related
									Not Related
					verapamil (C)	22-MAR-1999	Pseudomonas infection	H	Not Related
									Not Related
						22-MAR-1999	Atrial fibrillation	H	Not Related
									Not Related
						17-NOV-1997	Hepatocellular carcinoma	H	
						10-SEP-1999	Hepatic failure	D	
						22-MAR-1999	Hepatocellular carcinoma	H	
						22-MAR-1999	Nausea	H	
						22-MAR-1999	Pseudomonas infection	H	
						22-MAR-1999	Atrial fibrillation	H	
					spironolactone (C)	17-NOV-1997	Hepatocellular carcinoma	H	

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						10-SEP-1999	Hepatic failure	D		
						22-MAR-1999	Hepatocellular carcinoma	H		
						22-MAR-1999	Nausea	H		
						22-MAR-1999	Pseudomonas infection	H		
						22-MAR-1999	Atrial fibrillation	H		
					alprazolam (C)	17-NOV-1997	Hepatocellular carcinoma	H		
					10-SEP-1999	Hepatic failure	D			
					22-MAR-1999	Hepatocellular carcinoma	H			
					22-MAR-1999	Nausea	H			
					22-MAR-1999	Pseudomonas infection	H			
					22-MAR-1999	Atrial fibrillation	H			
Product Name (Drug Type) 1) timolol maleate(S) - All 2) verapamil(C) 3) spironolactone(C) 4) alprazolam(C)										
98041589	22-Apr-1998	0954-147	5048	Report From Study	Study Drug	Placebo (S)	15-APR-1998	Cerebral infarction	H	Not Related
		0305	5048	Clinical Trial						Not Related

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					16-APR-1998	Diabetes mellitus inadequate control	H	Not Related
					16-APR-1998	Blood pressure inadequately controlled	H	Not Related
					15-APR-1998	Cerebral infarction	H	Not Related
				voglibose (C)	16-APR-1998	Diabetes mellitus inadequate control	H	
					16-APR-1998	Blood pressure inadequately controlled	H	
				dipyridamole (C)	15-APR-1998	Cerebral infarction	H	
					16-APR-1998	Diabetes mellitus inadequate control	H	
					16-APR-1998	Blood pressure inadequately controlled	H	
				benidipine hydrochloride	15-APR-1998	Cerebral infarction	H	

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(C)									
						16-APR-1998	Diabetes mellitus inadequate control	H	
						16-APR-1998	Blood pressure inadequately controlled	H	
				epalrestat (C)		15-APR-1998	Cerebral infarction	H	
						16-APR-1998	Diabetes mellitus inadequate control	H	
						16-APR-1998	Blood pressure inadequately controlled	H	
				camostat (C)		15-APR-1998	Cerebral infarction	H	
						16-APR-1998	Diabetes mellitus inadequate control	H	
						16-APR-1998	Blood pressure inadequately controlled	H	

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				0950	timolol maleate (C)	15-APR-1998	Cerebral infarction	H	
						16-APR-1998	Diabetes mellitus inadequate control	H	
						16-APR-1998	Blood pressure inadequately controlled	H	
					pirenoxine (C)	15-APR-1998	Cerebral infarction	H	
						16-APR-1998	Diabetes mellitus inadequate control	H	
						16-APR-1998	Blood pressure inadequately controlled	H	
					insulin (C)	15-APR-1998	Cerebral infarction	H	
						16-APR-1998	Diabetes mellitus inadequate control	H	
						16-APR-1998	Blood pressure inadequately controlled	H	

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<div>Product Name (Drug Type)</div> <div>- All</div> <div>1) Placebo(S)</div> <div>2) voglibose(C)</div> <div>3) dipyridamole(C)</div> <div>4) benidipine hydrochloride(C)</div> <div>5) epalrestat(C)</div> <div>6) camostat(C)</div> <div>7) timolol maleate(C)</div> <div>8) pirenoxine(C)</div> <div>9) insulin(C)</div>										
98081374	18-Aug-1998	0954-147	5048	Report From Study	Study Drug Placebo (S)	15-AUG-1998	Acute myocardial infarction	H	Not Related	
		0305	5048	Clinical Trial		26-AUG-1998	Cholecystitis acute	H	Not Related	
						17-AUG-1998	Acute kidney injury	H	Not Related	
						13-AUG-1998	Angina unstable	H	Not Related	
									Not Related	
									Not Related	
									Not Related	

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					dipyridamole (C)	15-AUG-1998	Acute myocardial infarction	H	
						26-AUG-1998	Cholecystitis acute	H	
						17-AUG-1998	Acute kidney injury	H	
						13-AUG-1998	Angina unstable	H	
					benidipine hydrochloride (C)	15-AUG-1998	Acute myocardial infarction	H	
						26-AUG-1998	Cholecystitis acute	H	
						17-AUG-1998	Acute kidney injury	H	
						13-AUG-1998	Angina unstable	H	
					epalrestat (C)	15-AUG-1998	Acute myocardial infarction	H	
						26-AUG-1998	Cholecystitis acute	H	
						17-AUG-1998	Acute kidney injury	H	

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						13-AUG-1998	Angina unstable	H	
					camostat (C)	15-AUG-1998	Acute myocardial infarction	H	
						26-AUG-1998	Cholecystitis acute	H	
						17-AUG-1998	Acute kidney injury	H	
						13-AUG-1998	Angina unstable	H	
				0950	timolol maleate (C)	15-AUG-1998	Acute myocardial infarction	H	
						26-AUG-1998	Cholecystitis acute	H	
						17-AUG-1998	Acute kidney injury	H	
						13-AUG-1998	Angina unstable	H	
					pirenoxine (C)	15-AUG-1998	Acute myocardial infarction	H	
						26-AUG-1998	Cholecystitis acute	H	
						17-AUG-1998	Acute kidney injury	H	

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					13-AUG-1998	Angina unstable H	
				allopurinol (C)	15-AUG-1998	Acute myocardial infarction H	
					26-AUG-1998	Cholecystitis acute H	
					17-AUG-1998	Acute kidney injury H	
					13-AUG-1998	Angina unstable H	
				carvedilol (C)	15-AUG-1998	Acute myocardial infarction H	
					26-AUG-1998	Cholecystitis acute H	
					17-AUG-1998	Acute kidney injury H	
					13-AUG-1998	Angina unstable H	
				indapamide (C)	15-AUG-1998	Acute myocardial infarction H	
					26-AUG-1998	Cholecystitis acute H	

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						17-AUG-1998	Acute kidney injury	H	
						13-AUG-1998	Angina unstable	H	
					clonidine hydrochloride (C)	15-AUG-1998	Acute myocardial infarction	H	
						26-AUG-1998	Cholecystitis acute	H	
						17-AUG-1998	Acute kidney injury	H	
						13-AUG-1998	Angina unstable	H	
					aspirin (C)	15-AUG-1998	Acute myocardial infarction	H	
						26-AUG-1998	Cholecystitis acute	H	
						17-AUG-1998	Acute kidney injury	H	
						13-AUG-1998	Angina unstable	H	
					insulin (C)	15-AUG-1998	Acute myocardial infarction	H	
						26-AUG-1998	Cholecystitis acute	H	

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						17-AUG-1998	Acute kidney injury	H		
						13-AUG-1998	Angina unstable	H		
					imidapril hydrochloride (C)	15-AUG-1998	Acute myocardial infarction	H		
						26-AUG-1998	Cholecystitis acute	H		
						17-AUG-1998	Acute kidney injury	H		
						13-AUG-1998	Angina unstable	H		
<div>Product Name (Drug Type)</div> <div>- All</div> <div>1) Placebo(S)</div> <div>2) voglibose(C)</div> <div>3) dipyridamole(C)</div> <div>4) benidipine hydrochloride(C)</div> <div>5) epalrestat(C)</div> <div>6) camostat(C)</div> <div>7) timolol maleate(C)</div> <div>8) pirenoxine(C)</div> <div>9) allopurinol(C)</div> <div>10) carvedilol(C)</div> <div>11) indapamide(C)</div> <div>12) clonidine hydrochloride(C)</div> <div>13) aspirin(C)</div> <div>14) insulin(C)</div> <div>15) imidapril hydrochloride(C)</div>										
98090266	01-Sep-1998	0954-147	1636	Report From Study	Study Drug	Placebo (S)	05-DEC-1999	Acute kidney injury	H	Not Related

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		0025	1636		Clinical Trial				Not Related
						03-SEP-1998	Anaemia	H	Not Related
						31-AUG-1998	Myocardial infarction	H	Not Related
						31-AUG-1998	Cardiac failure congestive	H	Not Related
									Not Related
					furosemide (C)	05-DEC-1999	Acute kidney injury	H	
						03-SEP-1998	Anaemia	H	
						31-AUG-1998	Myocardial infarction	H	
						31-AUG-1998	Cardiac failure congestive	H	
					glyburide (C)	05-DEC-1999	Acute kidney injury	H	
						03-SEP-1998	Anaemia	H	
						31-AUG-1998	Myocardial infarction	H	
						31-AUG-1998	Cardiac failure congestive	H	
					aspirin (C)	05-DEC-1999	Acute kidney injury	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						03-SEP-1998	Anaemia	H	
						31-AUG-1998	Myocardial infarction	H	
						31-AUG-1998	Cardiac failure congestive	H	
					doxazosin monomethanesulfonate (C)	05-DEC-1999	Acute kidney injury	H	
						03-SEP-1998	Anaemia	H	
						31-AUG-1998	Myocardial infarction	H	
						31-AUG-1998	Cardiac failure congestive	H	
					penicillin V potassium salt (C)	05-DEC-1999	Acute kidney injury	H	
						03-SEP-1998	Anaemia	H	
						31-AUG-1998	Myocardial infarction	H	
						31-AUG-1998	Cardiac failure congestive	H	
					pilocarpine (C)	05-DEC-1999	Acute kidney injury	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						03-SEP-1998	Anaemia	H	
						31-AUG-1998	Myocardial infarction	H	
						31-AUG-1998	Cardiac failure congestive	H	
				0507	dorzolamide hydrochloride (C)	05-DEC-1999	Acute kidney injury	H	
						03-SEP-1998	Anaemia	H	
						31-AUG-1998	Myocardial infarction	H	
						31-AUG-1998	Cardiac failure congestive	H	
				0950	timolol maleate (C)	05-DEC-1999	Acute kidney injury	H	
						03-SEP-1998	Anaemia	H	
						31-AUG-1998	Myocardial infarction	H	
						31-AUG-1998	Cardiac failure congestive	H	
					labetalol (C)	05-DEC-1999	Acute kidney injury	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					03-SEP-1998	Anaemia	H	
					31-AUG-1998	Myocardial infarction	H	
					31-AUG-1998	Cardiac failure congestive	H	
				amlodipine (C)	05-DEC-1999	Acute kidney injury	H	
					03-SEP-1998	Anaemia	H	
					31-AUG-1998	Myocardial infarction	H	
					31-AUG-1998	Cardiac failure congestive	H	
				atorvastatin (C)	05-DEC-1999	Acute kidney injury	H	
					03-SEP-1998	Anaemia	H	
					31-AUG-1998	Myocardial infarction	H	
					31-AUG-1998	Cardiac failure congestive	H	
				sulfamethoxazole (+) trimethoprim (S)	05-DEC-1999	Acute kidney injury	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						03-SEP-1998	Anaemia	H	
						31-AUG-1998	Myocardial infarction	H	
						31-AUG-1998	Cardiac failure congestive	H	
Product Name (Drug Type) - All 1) Placebo(S) 2) furosemide(C) 3) glyburide(C) 4) aspirin(C) 5) doxazosin monomethanesulfonate(C) 6) penicillin V potassium salt(C) 7) pilocarpine(C) 8) dorzolamide hydrochloride(C) 9) timolol maleate(C) 10) labetalol(C) 11) amlodipine(C) 12) atorvastatin(C) 13) sulfamethoxazole (+) trimethoprim(S)									
99016108	22-Jan-1999		Spontaneous	0950E	timolol maleate (+) pilocarpine hydrochloride (S)	JUN-1998	Psoriasis	-	Related
									Related
Product Name (Drug Type) - All 1) timolol maleate (+) pilocarpine hydrochloride(S)									
99041503	14-Apr-1999		Literature Marketed	0507	dorzolamide hydrochloride (S)		Corneal decompensation	MS	Unknown
					dipivefrin (C)		Corneal decompensation	MS	Not Assessed

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality	
				0950	timolol maleate (C)		Corneal decompensatio n	MS		
		Product Name (Drug Type) 1) dorzolamide hydrochloride(S) - All 2) dipivefrin(C) 3) timolol maleate(C)								
99045163	26-Apr-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)	20-APR-1999	Conjunctivitis	-	Related	
									Related	
		Product Name (Drug Type) 1) dorzolamide hydrochloride (+) timolol maleate(S) - All								
99050422	22-Jun-1998	0954-147	1436	Report From Study	Study Drug	Placebo (S)	17-JUN-1998	End stage renal disease	H, DIS	Not Related
		0014	1436	Clinical Trial						Not Related
							08-MAR-2000	Gangrene	DIS	Not Related
							27-APR-1998	Chronic kidney disease	DIS	Not Related
										Not Related
							19-MAY-1999	Localised infection	H	Not Related
										Not Related
							09-APR-1999	Device related infection	H	Not Related
										Not Related
							29-JAN-1999	Vascular access complication	H	Not Related
										Not Related
							22-FEB-1999	Osteomyelitis	H	Not Related
										Not Related

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					captopril (C)	17-JUN-1998	End stage renal disease	H, DIS	
						08-MAR-2000	Gangrene	DIS	
						27-APR-1998	Chronic kidney disease	DIS	
						19-MAY-1999	Localised infection	H	
						09-APR-1999	Device related infection	H	
						29-JAN-1999	Vascular access complication	H	
						22-FEB-1999	Osteomyelitis	H	
					troglitazone (C)	17-JUN-1998	End stage renal disease	H, DIS	
						08-MAR-2000	Gangrene	DIS	
						27-APR-1998	Chronic kidney disease	DIS	
						19-MAY-1999	Localised infection	H	
						09-APR-1999	Device related infection	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					29-JAN-1999	Vascular access complication	H	
					22-FEB-1999	Osteomyelitis	H	
				glimepiride (C)	17-JUN-1998	End stage renal disease	H, DIS	
					08-MAR-2000	Gangrene	DIS	
					27-APR-1998	Chronic kidney disease	DIS	
					19-MAY-1999	Localised infection	H	
					09-APR-1999	Device related infection	H	
					29-JAN-1999	Vascular access complication	H	
					22-FEB-1999	Osteomyelitis	H	
				pravastatin sodium (C)	17-JUN-1998	End stage renal disease	H, DIS	
					08-MAR-2000	Gangrene	DIS	
					27-APR-1998	Chronic kidney disease	DIS	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						19-MAY-1999	Localised infection	H	
						09-APR-1999	Device related infection	H	
						29-JAN-1999	Vascular access complication	H	
						22-FEB-1999	Osteomyelitis	H	
				diphenoxylate (C)		17-JUN-1998	End stage renal disease	H, DIS	
						08-MAR-2000	Gangrene	DIS	
						27-APR-1998	Chronic kidney disease	DIS	
						19-MAY-1999	Localised infection	H	
						09-APR-1999	Device related infection	H	
						29-JAN-1999	Vascular access complication	H	
						22-FEB-1999	Osteomyelitis	H	
				diltiazem (C)		17-JUN-1998	End stage renal disease	H, DIS	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					08-MAR-2000	Gangrene	DIS	
					27-APR-1998	Chronic kidney disease	DIS	
					19-MAY-1999	Localised infection	H	
					09-APR-1999	Device related infection	H	
					29-JAN-1999	Vascular access complication	H	
					22-FEB-1999	Osteomyelitis	H	
				clonidine (C)	17-JUN-1998	End stage renal disease	H, DIS	
					08-MAR-2000	Gangrene	DIS	
					27-APR-1998	Chronic kidney disease	DIS	
					19-MAY-1999	Localised infection	H	
					09-APR-1999	Device related infection	H	
					29-JAN-1999	Vascular access complication	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						22-FEB-1999	Osteomyelitis	H	
					furosemide (C)	17-JUN-1998	End stage renal disease	H, DIS	
						08-MAR-2000	Gangrene	DIS	
						27-APR-1998	Chronic kidney disease	DIS	
						19-MAY-1999	Localised infection	H	
						09-APR-1999	Device related infection	H	
						29-JAN-1999	Vascular access complication	H	
						22-FEB-1999	Osteomyelitis	H	
					apraclonidine (C)	17-JUN-1998	End stage renal disease	H, DIS	
						08-MAR-2000	Gangrene	DIS	
						27-APR-1998	Chronic kidney disease	DIS	
						19-MAY-1999	Localised infection	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					09-APR-1999	Device related infection	H	
					29-JAN-1999	Vascular access complication	H	
					22-FEB-1999	Osteomyelitis	H	
				betaxolol hydrochloride (C)	17-JUN-1998	End stage renal disease	H, DIS	
					08-MAR-2000	Gangrene	DIS	
					27-APR-1998	Chronic kidney disease	DIS	
					19-MAY-1999	Localised infection	H	
					09-APR-1999	Device related infection	H	
					29-JAN-1999	Vascular access complication	H	
					22-FEB-1999	Osteomyelitis	H	
				glyburide (C)	17-JUN-1998	End stage renal disease	H, DIS	
					08-MAR-2000	Gangrene	DIS	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					27-APR-1998	Chronic kidney disease	DIS	
					19-MAY-1999	Localised infection	H	
					09-APR-1999	Device related infection	H	
					29-JAN-1999	Vascular access complication	H	
					22-FEB-1999	Osteomyelitis	H	
				vitamins (unspecified) (C)	17-JUN-1998	End stage renal disease	H, DIS	
					08-MAR-2000	Gangrene	DIS	
					27-APR-1998	Chronic kidney disease	DIS	
					19-MAY-1999	Localised infection	H	
					09-APR-1999	Device related infection	H	
					29-JAN-1999	Vascular access complication	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						22-FEB-1999	Osteomyelitis	H	
					gemfibrozil (C)	17-JUN-1998	End stage renal disease	H, DIS	
						08-MAR-2000	Gangrene	DIS	
						27-APR-1998	Chronic kidney disease	DIS	
						19-MAY-1999	Localised infection	H	
						09-APR-1999	Device related infection	H	
						29-JAN-1999	Vascular access complication	H	
						22-FEB-1999	Osteomyelitis	H	
					L-thyroxine (C)	17-JUN-1998	End stage renal disease	H, DIS	
						08-MAR-2000	Gangrene	DIS	
						27-APR-1998	Chronic kidney disease	DIS	
						19-MAY-1999	Localised infection	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term Seriousness Criteria	Reported Causality Determined Causality
					09-APR-1999	Device related infection	H
					29-JAN-1999	Vascular access complication	H
					22-FEB-1999	Osteomyelitis	H
				aspirin (C)	17-JUN-1998	End stage renal disease	H, DIS
					08-MAR-2000	Gangrene	DIS
					27-APR-1998	Chronic kidney disease	DIS
					19-MAY-1999	Localised infection	H
					09-APR-1999	Device related infection	H
					29-JAN-1999	Vascular access complication	H
					22-FEB-1999	Osteomyelitis	H
				0950 timolol maleate (C)	17-JUN-1998	End stage renal disease	H, DIS
					08-MAR-2000	Gangrene	DIS

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					27-APR-1998	Chronic kidney disease	DIS	
					19-MAY-1999	Localised infection	H	
					09-APR-1999	Device related infection	H	
					29-JAN-1999	Vascular access complication	H	
					22-FEB-1999	Osteomyelitis	H	
				calcium supplement (unspecified) (C)	17-JUN-1998	End stage renal disease	H, DIS	
					08-MAR-2000	Gangrene	DIS	
					27-APR-1998	Chronic kidney disease	DIS	
					19-MAY-1999	Localised infection	H	
					09-APR-1999	Device related infection	H	
					29-JAN-1999	Vascular access complication	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						22-FEB-1999	Osteomyelitis	H	
					acetaminophen (+) codeine phosphate (C)	17-JUN-1998	End stage renal disease	H, DIS	
						08-MAR-2000	Gangrene	DIS	
						27-APR-1998	Chronic kidney disease	DIS	
						19-MAY-1999	Localised infection	H	
						09-APR-1999	Device related infection	H	
						29-JAN-1999	Vascular access complication	H	
						22-FEB-1999	Osteomyelitis	H	
					rosiglitazone maleate (C)	17-JUN-1998	End stage renal disease	H, DIS	
						08-MAR-2000	Gangrene	DIS	
						27-APR-1998	Chronic kidney disease	DIS	
						19-MAY-1999	Localised infection	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term Seriousness Criteria	Reported Causality Determined Causality
					09-APR-1999	Device related infection	H
					29-JAN-1999	Vascular access complication	H
					22-FEB-1999	Osteomyelitis	H
				morphine sulfate (C)	17-JUN-1998	End stage renal disease	H, DIS
					08-MAR-2000	Gangrene	DIS
					27-APR-1998	Chronic kidney disease	DIS
					19-MAY-1999	Localised infection	H
					09-APR-1999	Device related infection	H
					29-JAN-1999	Vascular access complication	H
					22-FEB-1999	Osteomyelitis	H
				metronidazole (C)	17-JUN-1998	End stage renal disease	H, DIS
					08-MAR-2000	Gangrene	DIS

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					27-APR-1998	Chronic kidney disease	DIS	
					19-MAY-1999	Localised infection	H	
					09-APR-1999	Device related infection	H	
					29-JAN-1999	Vascular access complication	H	
					22-FEB-1999	Osteomyelitis	H	
				cephalexin (C)	17-JUN-1998	End stage renal disease	H, DIS	
					08-MAR-2000	Gangrene	DIS	
					27-APR-1998	Chronic kidney disease	DIS	
					19-MAY-1999	Localised infection	H	
					09-APR-1999	Device related infection	H	
					29-JAN-1999	Vascular access complication	H	
					22-FEB-1999	Osteomyelitis	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					pentoxifylline (C)	17-JUN-1998	End stage renal disease	H, DIS	
						08-MAR-2000	Gangrene	DIS	
						27-APR-1998	Chronic kidney disease	DIS	
						19-MAY-1999	Localised infection	H	
						09-APR-1999	Device related infection	H	
						29-JAN-1999	Vascular access complication	H	
						22-FEB-1999	Osteomyelitis	H	
					permethrin (C)	17-JUN-1998	End stage renal disease	H, DIS	
						08-MAR-2000	Gangrene	DIS	
						27-APR-1998	Chronic kidney disease	DIS	
						19-MAY-1999	Localised infection	H	
						09-APR-1999	Device related infection	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						29-JAN-1999	Vascular access complication	H	
						22-FEB-1999	Osteomyelitis	H	
					fluocinonide (C)	17-JUN-1998	End stage renal disease	H, DIS	
						08-MAR-2000	Gangrene	DIS	
						27-APR-1998	Chronic kidney disease	DIS	
						19-MAY-1999	Localised infection	H	
						09-APR-1999	Device related infection	H	
						29-JAN-1999	Vascular access complication	H	
						22-FEB-1999	Osteomyelitis	H	

Product Name (Drug Type)

- All

- 1) Placebo(S)
- 2) captopril(C)
- 3) troglitazone(C)
- 4) glimepiride(C)
- 5) pravastatin sodium(C)
- 6) diphenoxylate(C)
- 7) diltiazem(C)
- 8) clonidine(C)
- 9) furosemide(C)

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term Seriousness Criteria	Reported Causality Determined Causality
10) apraclonidine(C) 11) betaxolol hydrochloride(C) 12) glyburide(C) 13) vitamins (unspecified)(C) 14) gemfibrozil(C) 15) L-thyroxine(C) 16) aspirin(C) 17) timolol maleate(C) 18) calcium supplement (unspecified)(C) 19) acetaminophen (+) codeine phosphate(C) 20) rosiglitazone maleate(C) 21) morphine sulfate(C) 22) metronidazole(C) 23) cephalexin(C) 24) pentoxifylline(C) 25) permethrin(C) 26) fluocinonide(C)							
99051372	21-May-1999		Spontaneous	0950	timolol maleate (S)	General symptom -	Unknown
						Ocular discomfort -	Not Assessed
						Product residue present -	Unknown
							Not Assessed
Product Name (Drug Type) 1) timolol maleate(S) - All							
99060341	14-Apr-1999		Literature Marketed	0507	dorzolamide hydrochloride (S)	Corneal decompensation MS	Related
				0950	timolol maleate (C)	Corneal decompensation MS	Related

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					pilocarpine (C)		Corneal decompensatio n	MS	
					methazolamide (C)		Corneal decompensatio n	MS	
Product Name (Drug Type) - All					1) dorzolamide hydrochloride(S) 2) timolol maleate(C) 3) pilocarpine(C) 4) methazolamide(C)				
99060343	14-Apr-1999		Literature Marketed	0507	dorzolamide hydrochloride (S)		Corneal decompensatio n	MS	Related
									Related
					0950	timolol maleate (C)	Corneal decompensatio n	MS	
Product Name (Drug Type) - All					1) dorzolamide hydrochloride(S) 2) timolol maleate(C)				
99061970	28-Jun-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)		Periorbital pain	-	Unknown
									Not Assessed
							Burning sensation	-	Unknown
									Not Assessed
Product Name (Drug Type) - All					1) dorzolamide hydrochloride (+) timolol maleate(S)				
99070207	02-Jul-1999		Spontaneous	0733	simvastatin (S)		Neuropathy peripheral	-	Not Related

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
									Not Related
							Arthralgia	-	Unknown
									Not Assessed
				0950	timolol maleate (C)		Neuropathy peripheral	-	
							Arthralgia	-	
				0000	[therapy unspecified] (C)		Neuropathy peripheral	-	
							Arthralgia	-	
					phenylephrine hydrochloride (C)		Neuropathy peripheral	-	
							Arthralgia	-	
					clonazepam (C)		Neuropathy peripheral	-	
							Arthralgia	-	
					lorazepam (C)		Neuropathy peripheral	-	
							Arthralgia	-	
					loratadine (C)		Neuropathy peripheral	-	
							Arthralgia	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					nabumetone (C)		Neuropathy peripheral	-	
							Arthralgia	-	
Product Name (Drug Type) - All 1) simvastatin(S) 2) timolol maleate(C) 3) [therapy unspecified](C) 4) phenylephrine hydrochloride(C) 5) clonazepam(C) 6) lorazepam(C) 7) loratadine(C) 8) nabumetone(C)									
99080456	05-Aug-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)	01-AUG-1999	Sensation of foreign body	-	Unknown
									Not Assessed
						01-AUG-1999	Eye pain	-	Unknown
									Not Assessed
						01-AUG-1999	Eye discharge	-	Unknown
									Not Assessed
						01-AUG-1999	General symptom	-	Unknown
									Not Assessed
					conjugated estrogenic hormones (C)	01-AUG-1999	Sensation of foreign body	-	
						01-AUG-1999	Eye pain	-	
						01-AUG-1999	Eye discharge	-	
						01-AUG-1999	General symptom	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
<div> <div>Product Name (Drug Type)</div> <div>- All</div> <div> 1) dorzolamide hydrochloride (+) timolol maleate(S) 2) conjugated estrogenic hormones(C) 3) latanoprost(C) 4) timolol hemihydrate(C) </div> </div>									
99081180	16-Aug-1999		Spontaneous	0950	latanoprost (C)	01-AUG-1999	Sensation of foreign body	-	Unknown
						01-AUG-1999	Eye pain	-	
						01-AUG-1999	Eye discharge	-	
						01-AUG-1999	General symptom	-	
				9359	timolol hemihydrate (C)	01-AUG-1999	Sensation of foreign body	-	
						01-AUG-1999	Eye pain	-	
						01-AUG-1999	Eye discharge	-	
						01-AUG-1999	General symptom	-	
					timolol maleate (S)		Eye irritation	-	Not Assessed
					atenolol (C)		Eye irritation	-	
					furosemide (C)		Eye irritation	-	
					amlodipine benzenesulfona		Eye irritation	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
te (C)									
Product Name (Drug Type) - All									
99081369	18-Aug-1999		Spontaneous	0950	1) timolol maleate(S) 2) atenolol(C) 3) furosemide(C) 4) amlodipine benzenesulfonate(C)	AUG-1999	Asthenia	-	Not Related
					timolol maleate (S)				Not Related
					enalapril maleate (C)	AUG-1999	Asthenia	-	
					fluoxetine hydrochloride (S)	AUG-1999	Asthenia	-	
					glipizide (C)	AUG-1999	Asthenia	-	
					Product Name (Drug Type) - All				
					1) timolol maleate(S) 2) enalapril maleate(C) 3) fluoxetine hydrochloride(S) 4) glipizide(C)				
					dorzolamide hydrochloride (+) timolol maleate (S)		Dyspnoea	-	Unknown
99082034	12-Aug-1999		Spontaneous	0507A					Not Assessed
									Unknown
									Not Assessed
									Unknown
									Not Assessed
									Unknown
									Not Assessed
									Unknown
									Not Assessed
									Unknown
									Not Assessed
									Unknown
									Not Assessed
									Unknown
									Not Assessed
									Unknown

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						Rash	-	Unknown Not Assessed
				diltiazem (C)		Dyspnoea	-	
						Sputum increased	-	
						Cough	-	
						Wheezing	-	
						Rash	-	
				0242	ranitidine (C)	Dyspnoea	-	
						Sputum increased	-	
						Cough	-	
						Wheezing	-	
						Rash	-	
					nitroglycerin (C)	Dyspnoea	-	
						Sputum increased	-	
						Cough	-	
						Wheezing	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
							Rash	-	
					glyburide (C)		Dyspnoea	-	
							Sputum increased	-	
							Cough	-	
							Wheezing	-	
							Rash	-	
				0421	enalapril maleate (C)		Dyspnoea	-	
							Sputum increased	-	
							Cough	-	
							Wheezing	-	
							Rash	-	
					latanoprost (C)		Dyspnoea	-	
							Sputum increased	-	
							Cough	-	
							Wheezing	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
							Rash	-	
Product Name (Drug Type) 1) dorzolamide hydrochloride (+) timolol maleate(S) - All 2) diltiazem(C) 3) ranitidine(C) 4) nitroglycerin(C) 5) glyburide(C) 6) enalapril maleate(C) 7) latanoprost(C)									
99082255	30-Aug-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)	15-AUG-1999	Eye irritation	-	Unknown
						15-AUG-1999	Eye pain	-	Not Assessed Unknown Not Assessed
					brimonidine D-tartrate (C)	15-AUG-1999	Eye irritation	-	
						15-AUG-1999	Eye pain	-	
					conjugated estrogenic hormones (C)	15-AUG-1999	Eye irritation	-	
						15-AUG-1999	Eye pain	-	
					tolterodine (C)	15-AUG-1999	Eye irritation	-	
						15-AUG-1999	Eye pain	-	
Product Name (Drug Type) 1) dorzolamide hydrochloride (+) timolol maleate(S) - All 2) brimonidine D-tartrate(C) 3) conjugated estrogenic hormones(C) 4) tolterodine(C)									

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
99090399	07-Sep-1999		Spontaneous	0950	timolol maleate (S)	AUG-1999	Eye pain	-	Unknown
									Not Assessed
						AUG-1999	Conjunctival hyperaemia	-	Unknown
				0217	vitamins (C)	1998	Blepharitis	-	Not Assessed
									Not Related
						AUG-1999	Eye pain	-	Not Related
						AUG-1999	Conjunctival hyperaemia	-	
						1998	Blepharitis	-	
99091178	13-Sep-1999		Spontaneous	0950	timolol maleate (S)	AUG-1999	Eye pain	-	Unknown
									Not Assessed
						AUG-1999	Conjunctival hyperaemia	-	
99091526	21-Sep-1999		Spontaneous	0950	timolol maleate (S)				
							Product administration error	-	Unknown
									Not Assessed

Product Name (Drug Type) 1) timolol maleate(S)
- All 2) vitamins(C)
3) alendronate sodium(C)

Product Name (Drug Type) 1) timolol maleate(S)
- All

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
				0360A	thiabendazole (+) dexamethasone (+) neomycin sulfate (S)		Product administration error	-	Related
					prednisolone acetate (C)		Product administration error	-	Related
Product Name (Drug Type) 1) timolol maleate(S) - All 2) thiabendazole (+) dexamethasone (+) neomycin sulfate(S) 3) prednisolone acetate(C)									
99092107	28-Sep-1999		Spontaneous	0950	timolol maleate (S)	28-SEP-1999	Product residue present	-	Unknown
						28-SEP-1999	Eye pain	-	Not Assessed
Product Name (Drug Type) 1) timolol maleate(S) - All									
99092240	29-Sep-1999		Spontaneous	0950	timolol maleate (S)	1999	Eye irritation	-	Unknown
						1999	Eye pain	-	Not Assessed
Product Name (Drug Type) 1) timolol maleate(S) - All									
99095078	02-Aug-1999	0954-164	9726	Report From Study	Study Drug	02-DEC-1999	Myocardial infarction	D, LT	Not Related
		0289	9726	Clinical Trial		21-APR-1998	Cardiac failure congestive	H	Not Related
					furosemide (C)	02-DEC-1999	Myocardial infarction	D, LT	Not Related

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						21-APR-1998	Cardiac failure congestive	H	
					acetaminophen (+) propoxyphene napsylate monohydrate (C)	02-DEC-1999	Myocardial infarction	D, LT	
						21-APR-1998	Cardiac failure congestive	H	
					diclofenac (C)	02-DEC-1999	Myocardial infarction	D, LT	
						21-APR-1998	Cardiac failure congestive	H	
					albuterol (C)	02-DEC-1999	Myocardial infarction	D, LT	
						21-APR-1998	Cardiac failure congestive	H	
					pilocarpine (C)	02-DEC-1999	Myocardial infarction	D, LT	
						21-APR-1998	Cardiac failure congestive	H	
				0950	timolol maleate (C)	02-DEC-1999	Myocardial infarction	D, LT	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					21-APR-1998	Cardiac failure congestive	H	
				0421 enalapril maleate (C)	02-DEC-1999	Myocardial infarction	D, LT	
					21-APR-1998	Cardiac failure congestive	H	
Product Name (Drug Type) - All 1) losartan potassium(S) 2) furosemide(C) 3) acetaminophen (+) propoxyphene napsylate monohydrate(C) 4) diclofenac(C) 5) albuterol(C) 6) pilocarpine(C) 7) timolol maleate(C) 8) enalapril maleate(C)								
99096777	15-Sep-1999	0954-179	4912	Report From Study	captopril (S)	15-SEP-1999	Duodenal ulcer	H, LT
		0199	4912	Clinical Trial				
						30-SEP-1999	Peripheral ischaemia	H, DIS
						01-OCT-1999	Cardiac failure congestive	D, H, LT
						28-SEP-1999	Erysipelas	H
						13-SEP-1999	Anaemia	H
						13-SEP-1999	Dehydration	H
				9999	Placebo (C)	15-SEP-1999	Duodenal ulcer	H, LT

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						30-SEP-1999	Peripheral ischaemia	H, DIS	
						01-OCT-1999	Cardiac failure congestive	D, H, LT	
						28-SEP-1999	Erysipelas	H	
						13-SEP-1999	Anaemia	H	
						13-SEP-1999	Dehydration	H	
					isosorbide-5-mononitrate (C)	15-SEP-1999	Duodenal ulcer	H, LT	
						30-SEP-1999	Peripheral ischaemia	H, DIS	
						01-OCT-1999	Cardiac failure congestive	D, H, LT	
						28-SEP-1999	Erysipelas	H	
						13-SEP-1999	Anaemia	H	
						13-SEP-1999	Dehydration	H	
				0950E	timolol maleate (+) pilocarpine hydrochloride (C)	15-SEP-1999	Duodenal ulcer	H, LT	
						30-SEP-1999	Peripheral ischaemia	H, DIS	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					01-OCT-1999	Cardiac failure congestive	D, H, LT	
					28-SEP-1999	Erysipelas	H	
					13-SEP-1999	Anaemia	H	
					13-SEP-1999	Dehydration	H	
				furosemide (C)	15-SEP-1999	Duodenal ulcer	H, LT	
					30-SEP-1999	Peripheral ischaemia	H, DIS	
					01-OCT-1999	Cardiac failure congestive	D, H, LT	
					28-SEP-1999	Erysipelas	H	
					13-SEP-1999	Anaemia	H	
					13-SEP-1999	Dehydration	H	
				bisoprolol (C)	15-SEP-1999	Duodenal ulcer	H, LT	
					30-SEP-1999	Peripheral ischaemia	H, DIS	
					01-OCT-1999	Cardiac failure congestive	D, H, LT	
					28-SEP-1999	Erysipelas	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					13-SEP-1999	Anaemia	H	
					13-SEP-1999	Dehydration	H	
Product Name (Drug Type) 1) captopril(S) - All 2) Placebo(C) 3) isosorbide-5-mononitrate(C) 4) timolol maleate (+) pilocarpine hydrochloride(C) 5) furosemide(C) 6) bisoprolol(C)								
99100273	04-Oct-1999		Spontaneous	0966	rofecoxib (S)	Mouth ulceration	-	Unknown
						Eating disorder	-	Not Assessed
						Glossitis	-	Unknown
								Not Assessed
					aspirin (C)	Mouth ulceration	-	Unknown
						Eating disorder	-	Not Assessed
						Glossitis	-	Unknown
				0950	timolol maleate (C)	Mouth ulceration	-	Unknown
						Eating disorder	-	Not Assessed
						Glossitis	-	Unknown
					celecoxib (C)	Mouth ulceration	-	Unknown

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
							Eating disorder	-	
							Glossitis	-	
Product Name (Drug Type) 1) rofecoxib(S) - All 2) aspirin(C) 3) timolol maleate(C) 4) celecoxib(C)									
99100389	05-Oct-1999		Spontaneous	0950	timolol maleate (S)	01-OCT-1999	Eye oedema	-	Unknown
									Unknown
							01-OCT-1999	Eyelid disorder	Related
									Related
							latanoprost (C)	01-OCT-1999	Eye oedema -
								01-OCT-1999	Eyelid disorder -
							verapamil (C)	01-OCT-1999	Eye oedema -
								01-OCT-1999	Eyelid disorder -
Product Name (Drug Type) 1) timolol maleate(S) - All 2) latanoprost(C) 3) verapamil(C)									
99100950	12-Oct-1999		Spontaneous	0950	timolol maleate (S)		Eye pain	-	Unknown
									Not Assessed
							Eye inflammation	-	Unknown
									Not Assessed
							General symptom	-	Unknown
									Not Assessed
Product Name (Drug Type) 1) timolol maleate(S)									

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
- All									
99101315	15-Oct-1999		Spontaneous	0950	timolol maleate (S)	OCT-1998	Suicide attempt	D, LT	Unknown
Product Name (Drug Type) 1) timolol maleate(S)									Unknown
- All									
99102346	28-Oct-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)	05-OCT-1999	Dizziness	-	Unknown
									Not Assessed
							Dysgeusia	-	Unknown
									Not Assessed
						latanoprost (C)	05-OCT-1999	Dizziness	-
							Dysgeusia	-	
						clonazepam (C)	05-OCT-1999	Dizziness	-
							Dysgeusia	-	
Product Name (Drug Type) 1) dorzolamide hydrochloride (+) timolol maleate(S)									
- All									
2) latanoprost(C)									
3) clonazepam(C)									
99102443	16-Apr-1999		Spontaneous	0950	timolol maleate (S)		Eye irritation	-	Unknown
									Not Assessed
				0803	lovastatin (C)		Eye irritation	-	
				0954	losartan potassium (C)		Eye irritation	-	
				0906	finasteride (C)		Eye irritation	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
				0421	enalapril maleate (C)		Eye irritation	-	
				9086	phytonadione (C)		Eye irritation	-	
				0950	timolol maleate (C)		Eye irritation	-	
Product Name (Drug Type) - All 1) timolol maleate(S) 2) lovastatin(C) 3) losartan potassium(C) 4) finasteride(C) 5) enalapril maleate(C) 6) phytonadione(C) 7) timolol maleate(C)									
99107276	13-Oct-1999	0954-925	40465	Report From Study	atenolol (S)	06-OCT-1999	Aortic dissection	H	
		0695	40465	Clinical Trial		06-OCT-1999	Spinal cord disorder	H, DIS	
						06-OCT-1999	Renal failure	H	
					9999	Placebo (C)	Aortic dissection	H	
						06-OCT-1999	Spinal cord disorder	H, DIS	
						06-OCT-1999	Renal failure	H	
					0152	hydrochlorothiazide (C)	Aortic dissection	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						06-OCT-1999	Spinal cord disorder	H, DIS	
						06-OCT-1999	Renal failure	H	
					warfarin (C)	06-OCT-1999	Aortic dissection	H	
						06-OCT-1999	Spinal cord disorder	H, DIS	
						06-OCT-1999	Renal failure	H	
					tenoxicam (C)	06-OCT-1999	Aortic dissection	H	
						06-OCT-1999	Spinal cord disorder	H, DIS	
						06-OCT-1999	Renal failure	H	
				0950	timolol maleate (C)	06-OCT-1999	Aortic dissection	H	
						06-OCT-1999	Spinal cord disorder	H, DIS	
						06-OCT-1999	Renal failure	H	
Product Name (Drug Type) - All <ul style="list-style-type: none"> 1) atenolol(S) 2) Placebo(C) 3) hydrochlorothiazide(C) 4) warfarin(C) 5) tenoxicam(C) 6) timolol maleate(C) 									

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
99110139	01-Nov-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)	27-SEP-1999	Eye allergy	-	Related
						27-SEP-1999	Dermatitis contact	-	Related
									Related
					brimonidine D-tartrate (S)	27-SEP-1999	Eye allergy	-	Related
						27-SEP-1999	Dermatitis contact	-	
						latanoprost (S)	27-SEP-1999	Eye allergy	-
					27-SEP-1999		Dermatitis contact	-	
					Product Name (Drug Type) - All		1) dorzolamide hydrochloride (+) timolol maleate(S) 2) brimonidine D-tartrate(S) 3) latanoprost(S)		
99110597	08-Nov-1999		Spontaneous	0217	alendronate sodium (S)		Nail disorder	-	Unknown
							Dyspepsia	-	Not Assessed
									Unknown
					0950	timolol maleate (C)	Nail disorder	-	Not Assessed
									Dyspepsia
latanoprost (C)		Nail disorder	-						

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
							Dyspepsia	-	
Product Name (Drug Type) - All									
99110774	10-Nov-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)	11-OCT-1999	Intraocular pressure increased	-	Related
				0950	timolol maleate (C)	11-OCT-1999	Intraocular pressure increased	-	Related
					pilocarpine (C)	11-OCT-1999	Intraocular pressure increased	-	
Product Name (Drug Type) - All									
99110918	11-Nov-1999		Spontaneous	0950	timolol maleate (S)	08-DEC-1995	Conjunctival hyperaemia	-	Related
						08-DEC-1995	Eye lid oedema	-	Related
						08-DEC-1995	Skin disorder	-	Related
						08-DEC-1995	Eye pruritus	-	Related
						08-DEC-1995	Hypersensitivity	-	Related
						08-DEC-1995	Periorbital oedema	-	Related
									Related

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
Product Name (Drug Type) 1) timolol maleate(S)									
- All									
99111239	16-Nov-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)		Corneal decompensation	MS	Related
									Unknown
						08-OCT-1999	Iritis	MS	Unknown
									Unknown
						NOV-1999	Keratic precipitates	MS	Unknown
									Unknown
						NOV-1999	Anterior chamber disorder	MS	Unknown
									Unknown
						08-OCT-1999	Corneal oedema	MS	Unknown
									Unknown
						NOV-1999	Hypotony of eye	MS	Unknown
									Unknown
							Uveitis	MS	Related
									Unknown
					ciprofloxacin monohydrochloride monohydrate (C)		Corneal decompensation	MS	
						08-OCT-1999	Iritis	MS	
						NOV-1999	Keratic precipitates	MS	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					NOV-1999	Anterior chamber disorder	MS	
					08-OCT-1999	Corneal oedema	MS	
					NOV-1999	Hypotony of eye	MS	
						Uveitis	MS	
				atropine (C)		Corneal decompensation	MS	
					08-OCT-1999	Iritis	MS	
					NOV-1999	Keratic precipitates	MS	
					NOV-1999	Anterior chamber disorder	MS	
					08-OCT-1999	Corneal oedema	MS	
					NOV-1999	Hypotony of eye	MS	
						Uveitis	MS	
				prednisolone acetate (C)		Corneal decompensation	MS	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term Seriousness Criteria	Reported Causality Determined Causality
					n		
					08-OCT-1999	Iritis	MS
					NOV-1999	Keratic precipitates	MS
					NOV-1999	Anterior chamber disorder	MS
					08-OCT-1999	Corneal oedema	MS
					NOV-1999	Hypotony of eye	MS
						Uveitis	MS
				diclofenac sodium (C)		Corneal decompensation	MS
					08-OCT-1999	Iritis	MS
					NOV-1999	Keratic precipitates	MS
					NOV-1999	Anterior chamber disorder	MS
					08-OCT-1999	Corneal oedema	MS

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						NOV-1999	Hypotony of eye	MS	
							Uveitis	MS	
					benzalkonium chloride (C)		Corneal decompensation	MS	
						08-OCT-1999	Iritis	MS	
						NOV-1999	Keratic precipitates	MS	
						NOV-1999	Anterior chamber disorder	MS	
						08-OCT-1999	Corneal oedema	MS	
						NOV-1999	Hypotony of eye	MS	
							Uveitis	MS	
Product Name (Drug Type) - All 1) dorzolamide hydrochloride (+) timolol maleate(S) 2) ciprofloxacin monohydrochloride monohydrate(C) 3) atropine(C) 4) prednisolone acetate(C) 5) diclofenac sodium(C) 6) benzalkonium chloride(C)									
99111693	23-Nov-1999		Spontaneous	0507	dorzolamide hydrochloride (S)	24-MAR-2000	Eye irritation	-	Unknown

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						24-MAR-2000	Eye pain	-	Not Assessed
						22-APR-2000	Eye pain	-	Unknown
						22-APR-2000	Lacrimation increased	-	Not Assessed
						20-NOV-1999	Visual impairment	-	Unknown
						24-MAR-2000	Eye irritation	-	Not Assessed
						24-MAR-2000	Eye pain	-	
						22-APR-2000	Eye pain	-	
						22-APR-2000	Lacrimation increased	-	
						20-NOV-1999	Visual impairment	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
- All		2) latanoprost(C)							
99115578	10-Nov-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)	23-OCT-1999	Diarrhoea	-	Related
						23-OCT-1999	Conjunctival hyperaemia	-	Unknown Related
						23-OCT-1999	Muscular weakness	-	Unknown Related
						23-OCT-1999	Tachycardia	-	Unknown Related Unknown
						23-OCT-1999	Painful respiration	-	Related Unknown
Product Name (Drug Type)		1) dorzolamide hydrochloride (+) timolol maleate(S)							
- All									
99116045	15-Nov-1999		Spontaneous	0950	timolol maleate (S)	JAN-1997	Conjunctivitis allergic	-	Related
									Related
Product Name (Drug Type)		1) timolol maleate(S)							
- All									
99120138	01-Dec-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)		Eye pain	-	Unknown
									Not Assessed
Product Name (Drug Type)		1) dorzolamide hydrochloride (+) timolol maleate(S)							
- All									
99120223	02-Dec-1999		Spontaneous	0507	dorzolamide hydrochloride (S)		Chest pain	-	Unknown
									Not Assessed

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						Sputum abnormal	-	Unknown
								Not Assessed
						Bacterial infection	-	Unknown
								Not Assessed
						Neck pain	-	Unknown
								Not Assessed
						Gastrointestinal disorder	-	Unknown
								Not Assessed
				insulin (C)		Chest pain	-	
						Sputum abnormal	-	
						Bacterial infection	-	
						Neck pain	-	
						Gastrointestinal disorder	-	
				acetaminophen (C)		Chest pain	-	
						Sputum abnormal	-	
						Bacterial infection	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
							Neck pain	-	
							Gastrointestinal disorder	-	
				0950	timolol maleate (C)		Chest pain	-	
							Sputum abnormal	-	
							Bacterial infection	-	
							Neck pain	-	
							Gastrointestinal disorder	-	
					latanoprost (C)		Chest pain	-	
							Sputum abnormal	-	
							Bacterial infection	-	
							Neck pain	-	
							Gastrointestinal disorder	-	
Product Name (Drug Type) 1) dorzolamide hydrochloride(S) - All 2) insulin(C)									

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
		3) acetaminophen(C) 4) timolol maleate(C) 5) latanoprost(C)							
99120348	04-Dec-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)		pH urine increased	-	Unknown
									Not Assessed
					latanoprost (C)		pH urine increased	-	
		Product Name (Drug Type) 1) dorzolamide hydrochloride (+) timolol maleate(S) - All 2) latanoprost(C)							
99120441	06-Dec-1999		Spontaneous	0950	timolol maleate (S)	SEP-1999	Nervousness	-	Unknown
									Not Assessed
						SEP-1999	Panic attack	-	Unknown
						SEP-1999	Ear congestion	-	Not Assessed
						SEP-1999	Ear congestion	-	Unknown
						SEP-1999	Ear congestion	-	Not Assessed
					saline (C)	SEP-1999	Nervousness	-	
						SEP-1999	Panic attack	-	
						SEP-1999	Ear congestion	-	
				0000	[therapy unspecified] (C)	SEP-1999	Nervousness	-	
						SEP-1999	Panic attack	-	
						SEP-1999	Ear congestion	-	
		Product Name (Drug Type) 1) timolol maleate(S)							

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality	
- All		2) saline(C) 3) [therapy unspecified](C)								
99120458	06-Dec-1999		Spontaneous	0950	timolol maleate (S)	1997	Muscular weakness	-	Unknown	
						1997	Pain in extremity	-	Not Assessed	
					latanoprost (C)	1997	Muscular weakness	-	Unknown	
						1997	Pain in extremity	-	Not Assessed	
Product Name (Drug Type)		1) timolol maleate(S) 2) latanoprost(C)								
- All										
99120520	07-Dec-1999	0950	34059	Report From Study	0950	timolol maleate (S)	28-SEP-1999	Urinary tract infection	-	Not Related
			34059	Clinical Trial						Not Related
Product Name (Drug Type)		1) timolol maleate(S)								
- All										
99120541	02-Dec-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)		Oropharyngeal pain	-	Unknown	
										Not Assessed
Product Name (Drug Type)		1) dorzolamide hydrochloride (+) timolol maleate(S)								
- All										
99120873	10-Dec-1999	0954-147	1471	Report From Study	Study Drug	Placebo (S)	01-DEC-1999	Bile duct cancer D, H, LT		Not Related
		0005	1471	Clinical Trial						Not Related
							01-DEC-1999	Chronic kidney disease	H	Not Related
										Not Related

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term Seriousness Criteria	Reported Causality Determined Causality
					furosemide (C)	01-DEC-1999	Bile duct cancer D, H, LT	
						01-DEC-1999	Chronic kidney H disease	
					nifedipine (C)	01-DEC-1999	Bile duct cancer D, H, LT	
						01-DEC-1999	Chronic kidney H disease	
					troglitazone (C)	01-DEC-1999	Bile duct cancer D, H, LT	
						01-DEC-1999	Chronic kidney H disease	
					vitamins (C)	01-DEC-1999	Bile duct cancer D, H, LT	
						01-DEC-1999	Chronic kidney H disease	
					glipizide (C)	01-DEC-1999	Bile duct cancer D, H, LT	
						01-DEC-1999	Chronic kidney H disease	
					allopurinol (C)	01-DEC-1999	Bile duct cancer D, H, LT	
						01-DEC-1999	Chronic kidney H disease	
					pravastatin sodium (C)	01-DEC-1999	Bile duct cancer D, H, LT	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term Seriousness Criteria	Reported Causality Determined Causality
						01-DEC-1999	Chronic kidney H disease	
					bumetanide (C)	01-DEC-1999	Bile duct cancer D, H, LT	
						01-DEC-1999	Chronic kidney H disease	
					terbinafine (C)	01-DEC-1999	Bile duct cancer D, H, LT	
						01-DEC-1999	Chronic kidney H disease	
					[composition unspecified] (C)	01-DEC-1999	Bile duct cancer D, H, LT	
						01-DEC-1999	Chronic kidney H disease	
					terazosin (C)	01-DEC-1999	Bile duct cancer D, H, LT	
						01-DEC-1999	Chronic kidney H disease	
				0950	timolol maleate (C)	01-DEC-1999	Bile duct cancer D, H, LT	
						01-DEC-1999	Chronic kidney H disease	
					betamethasone dipropionate (+) clotrimazole (C)	01-DEC-1999	Bile duct cancer D, H, LT	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						01-DEC-1999	Chronic kidney disease	H	
					garlic extract (C)	01-DEC-1999	Bile duct cancer	D, H, LT	
						01-DEC-1999	Chronic kidney disease	H	
Product Name (Drug Type) - All 1) Placebo(S) 2) furosemide(C) 3) nifedipine(C) 4) troglitazone(C) 5) vitamins(C) 6) glipizide(C) 7) allopurinol(C) 8) pravastatin sodium(C) 9) bumetanide(C) 10) terbinafine(C) 11) [composition unspecified](C) 12) terazosin(C) 13) timolol maleate(C) 14) betamethasone dipropionate (+) clotrimazole(C) 15) garlic extract(C)									
99120951	10-Dec-1999		Spontaneous	0950	timolol maleate (S)		Paraesthesia	-	Unknown
									Unknown
Product Name (Drug Type) - All 1) timolol maleate(S)									
99120979	13-Dec-1999		Spontaneous	0950	timolol maleate (S)	13-DEC-1999	Eye irritation	-	Unknown
									Not Assessed
						DEC-1999	Product residue present	-	Unknown
									Not Assessed

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality		
						13-DEC-1999	Eye irritation	-	Unknown Not Assessed		
						13-DEC-1999	General symptom	-	Unknown Not Assessed		
						13-DEC-1999	Pain	-	Unknown Not Assessed		
						13-DEC-1999	General symptom	-	Unknown Not Assessed		
						0521A	lisinopril (+) hydrochlorothiazide (C)	13-DEC-1999	Eye irritation	-	
						DEC-1999	Product residue present	-			
						13-DEC-1999	Eye irritation	-			
						13-DEC-1999	General symptom	-			
						13-DEC-1999	Pain	-			
						13-DEC-1999	General symptom	-			
Product Name (Drug Type) 1) timolol maleate(S) - All 2) lisinopril (+) hydrochlorothiazide(C)											
99121193	14-Dec-1999	0554-006	0327	Report From Study	Study Drug	MK-0554 (S)	30-DEC-1999	Myocardial infarction	D	Related	
		0002	0327	Clinical Trial						Related	
							01-DEC-1999	Electrocardiogram QT prolonged	H	Related	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality Related
					potassium chloride (C)	30-DEC-1999	Myocardial infarction	D	
						01-DEC-1999	Electrocardiogram QT prolonged	H	
				9334	acetazolamide (C)	30-DEC-1999	Myocardial infarction	D	
						01-DEC-1999	Electrocardiogram QT prolonged	H	
					fluoxetine hydrochloride (C)	30-DEC-1999	Myocardial infarction	D	
						01-DEC-1999	Electrocardiogram QT prolonged	H	
					calcium polycarbophil (C)	30-DEC-1999	Myocardial infarction	D	
						01-DEC-1999	Electrocardiogram QT prolonged	H	
					atropine sulfate (+) diphenoxylate hydrochloride	30-DEC-1999	Myocardial infarction	D	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					(C)				
						01-DEC-1999	Electrocardiogr am QT prolonged	H	
				0966	rofecoxib (C)	30-DEC-1999	Myocardial infarction	D	
						01-DEC-1999	Electrocardiogr am QT prolonged	H	
					[therapy unspecified] (C)	30-DEC-1999	Myocardial infarction	D	
						01-DEC-1999	Electrocardiogr am QT prolonged	H	
					pravastatin sodium (C)	30-DEC-1999	Myocardial infarction	D	
						01-DEC-1999	Electrocardiogr am QT prolonged	H	
				0950	timolol maleate (C)	30-DEC-1999	Myocardial infarction	D	
						01-DEC-1999	Electrocardiogr am QT prolonged	H	

Product Name (Drug Type) 1) MK-0554(S)

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
- All		2) potassium chloride(C) 3) acetazolamide(C) 4) fluoxetine hydrochloride(C) 5) calcium polycarbophil(C) 6) atropine sulfate (+) diphenoxylate hydrochloride(C) 7) rofecoxib(C) 8) [therapy unspecified](C) 9) pravastatin sodium(C) 10) timolol maleate(C)							
99121199	09-Dec-1999	0954-147	2080	Report From Study	Study Drug	losartan potassium (S)	29-SEP-1999	End stage renal H, DIS disease	Not Related
			2080	Clinical Trial			24-SEP-1999	Renal failure H	Not Related
		0004	2080			timolol maleate (C)	29-SEP-1999	End stage renal H, DIS disease	Not Related
							24-SEP-1999	Renal failure H	Not Related
						brimonidine D-tartrate (C)	29-SEP-1999	End stage renal H, DIS disease	Not Related
							24-SEP-1999	Renal failure H	Not Related
						calcitriol (C)	29-SEP-1999	End stage renal H, DIS disease	Not Related
							24-SEP-1999	Renal failure H	Not Related
						calcium carbonate (C)	29-SEP-1999	End stage renal H, DIS disease	Not Related
							24-SEP-1999	Renal failure H	Not Related
							29-SEP-1999	End stage renal H, DIS disease	Not Related
							24-SEP-1999	Renal failure H	Not Related

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					furosemide (C)	29-SEP-1999	End stage renal disease	H, DIS	
						24-SEP-1999	Renal failure	H	
					doxazosin (C)	29-SEP-1999	End stage renal disease	H, DIS	
						24-SEP-1999	Renal failure	H	
					insulin zinc suspension (C)	29-SEP-1999	End stage renal disease	H, DIS	
						24-SEP-1999	Renal failure	H	
					insulin (C)	29-SEP-1999	End stage renal disease	H, DIS	
						24-SEP-1999	Renal failure	H	
					diltiazem (C)	29-SEP-1999	End stage renal disease	H, DIS	
						24-SEP-1999	Renal failure	H	
Product Name (Drug Type) 1) losartan potassium(S) - All 2) timolol maleate(C) 3) brimonidine D-tartrate(C) 4) calcitriol(C) 5) calcium carbonate(C) 6) furosemide(C) 7) doxazosin(C) 8) insulin zinc suspension(C) 9) insulin(C) 10) diltiazem(C)									

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
99121237	15-Dec-1999		Spontaneous	0950	timolol maleate (S)	20-OCT-1999	Eye pain	MS	Related
									Related
						20-OCT-1999	Eye inflammation	MS	Related
					timolol maleate (C)	20-OCT-1999	Eye pain	MS	Related
						20-OCT-1999	Eye inflammation	MS	
Product Name (Drug Type) 1) timolol maleate(S) - All 2) timolol maleate(C)									
99121437	16-Dec-1999		Spontaneous	0966	rofecoxib (S)		Therapeutic response unexpected	-	Not Related
									Not Related
							No adverse event	-	Not Related
									Not Related
				0152	diltiazem d-cis form hydrochloride (C)		Therapeutic response unexpected	-	
							No adverse event	-	
				0152	hydrochlorothiazide (C)		Therapeutic response unexpected	-	
							No adverse event	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
				0950	timolol maleate (C)		Therapeutic response unexpected	-	
							No adverse event	-	
					acetaminophen (C)		Therapeutic response unexpected	-	
							No adverse event	-	
					loperamide (C)		Therapeutic response unexpected	-	
							No adverse event	-	
Product Name (Drug Type)			1) rofecoxib(S) 2) diltiazem d-cis form hydrochloride(C) 3) hydrochlorothiazide(C) 4) timolol maleate(C) 5) acetaminophen(C) 6) loperamide(C)						
- All									
99121529	17-Dec-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)	MAR-1999	Prostatic specific antigen increased	-	Unknown
									Not Assessed
				9355	allopurinol (C)	MAR-1999	Prostatic specific antigen	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
							increased		
					thyroid (C)	MAR-1999	Prostatic specific antigen increased	-	
					quinine sulfate (C)	MAR-1999	Prostatic specific antigen increased	-	
					doxazosin monomethanesulfonate (C)	MAR-1999	Prostatic specific antigen increased	-	
Product Name (Drug Type) 1) dorzolamide hydrochloride (+) timolol maleate(S) - All 2) allopurinol(C) 3) thyroid(C) 4) quinine sulfate(C) 5) doxazosin monomethanesulfonate(C)									
99121549	17-Dec-1999		Spontaneous	0950	timolol maleate (S)		Exfoliation syndrome	-	Unknown
									Not Assessed
Product Name (Drug Type) 1) timolol maleate(S) - All									
99121557	17-Dec-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)	JUL-1999	Dizziness	-	Unknown
						JUL-1999	Vision blurred	-	Not Assessed
									Unknown
									Not Assessed
					brimonidine D- tartrate (C)	JUL-1999	Dizziness	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
						JUL-1999	Vision blurred	-	
Product Name (Drug Type) 1) dorzolamide hydrochloride (+) timolol maleate(S) - All 2) brimonidine D-tartrate(C)									
99121665	20-Dec-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)	1999	Palpitations	-	Unknown
						1999	Alopecia	-	Not Assessed Unknown Not Assessed
Product Name (Drug Type) 1) dorzolamide hydrochloride (+) timolol maleate(S) - All									
99121749	17-Dec-1999		Spontaneous	0217	alendronate sodium (S)	1999	Diarrhoea	-	Unknown
						1999	Dysgeusia	-	Not Assessed Unknown Not Assessed
				0950	timolol maleate (C)	1999	Diarrhoea	-	
						1999	Dysgeusia	-	
					amlodipine benzenesulfonate (C)	1999	Diarrhoea	-	
						1999	Dysgeusia	-	
					benazepril hydrochloride (C)	1999	Diarrhoea	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality	
						1999	Dysgeusia	-		
Product Name (Drug Type) - All		1) alendronate sodium(S) 2) timolol maleate(C) 3) amlodipine benzenesulfonate(C) 4) benazepril hydrochloride(C)								
99121786	21-Dec-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)	30-NOV-1999	Vision blurred	-	Unknown	
									Not Assessed	
Product Name (Drug Type) - All		1) dorzolamide hydrochloride (+) timolol maleate(S)								
99121936	22-Dec-1999		Spontaneous	0950	timolol maleate (S)		Intraocular pressure increased	-	Unknown	
									Not Assessed	
									Unknown	
									Not Assessed	
Product Name (Drug Type) - All		1) timolol maleate(S)								
99122042	21-Dec-1999		Spontaneous	0950	timolol maleate (S)		Eye infection	-	Related	
									Related	
									Related	
									Related	
									Related	
Product Name (Drug Type) - All		1) timolol maleate(S)								
99122215	29-Dec-1999	0954-147	1482	Report From Study	Study Drug	losartan potassium (S)	27-DEC-1999	Bronchitis	H	Not Related
									Not Related	
		0006	1482	Clinical Trial						

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					clonidine (C)	27-DEC-1999	Bronchitis	H	
					furosemide (C)	27-DEC-1999	Bronchitis	H	
					insulin (C)	27-DEC-1999	Bronchitis	H	
					isophane insulin suspension (C)	27-DEC-1999	Bronchitis	H	
					pentoxifylline (C)	27-DEC-1999	Bronchitis	H	
					acetaminophen (C)	27-DEC-1999	Bronchitis	H	
					latanoprost (C)	27-DEC-1999	Bronchitis	H	
				0950	timolol maleate (C)	27-DEC-1999	Bronchitis	H	
				0208	famotidine (C)	27-DEC-1999	Bronchitis	H	
					terazosin (C)	27-DEC-1999	Bronchitis	H	
					vitamin E (C)	27-DEC-1999	Bronchitis	H	
Product Name (Drug Type) 1) losartan potassium(S) - All 2) clonidine(C) 3) furosemide(C) 4) insulin(C) 5) isophane insulin suspension(C) 6) pentoxifylline(C) 7) acetaminophen(C) 8) latanoprost(C)									

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
99122244	29-Dec-1999		Spontaneous	0966	rofecoxib (S)		Cough	-	Unknown Not Assessed
							Pruritus	-	Unknown Not Assessed
							Swelling	-	Unknown Not Assessed
							Cough	-	
							Pruritus	-	
							Swelling	-	
					calcitonin, salmon synthetic (C)		Cough	-	
							Pruritus	-	
							Swelling	-	
					calcium supplement (composition unspecified) (C)		Cough	-	
							Pruritus	-	
							Swelling	-	
				0950	timolol maleate (C)		Cough	-	
							Pruritus	-	
							Swelling	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
Product Name (Drug Type) 1) rofecoxib(S) - All 2) calcitonin, salmon synthetic(C) 3) calcium supplement (composition unspecified)(C) 4) timolol maleate(C)									
99122272	28-Dec-1999	0966-091	0719	Report From Study	Study Drug Placebo (S)	26-DEC-1999	Pneumonia	H	Not Related
		0031	0719	Clinical Trial		26-DEC-1999	Respiratory distress	H, LT	Not Related
						26-DEC-1999	Pneumonia	H	Not Related
						26-DEC-1999	Respiratory distress	H, LT	Not Related
		donepezil hydrochloride (C)	26-DEC-1999	Pneumonia	H				
			26-DEC-1999	Respiratory distress	H, LT				
			levothyroxine sodium (C)	26-DEC-1999	Pneumonia	H			
				26-DEC-1999	Respiratory distress	H, LT			
			diltiazem (C)	26-DEC-1999	Pneumonia	H			
				26-DEC-1999	Respiratory distress	H, LT			
			[therapy unspecified] (C)	26-DEC-1999	Pneumonia	H			
26-DEC-1999	Respiratory distress	H, LT							

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					calcium supplement (composition unspecified) (C)	26-DEC-1999	Pneumonia	H	
						26-DEC-1999	Respiratory distress	H, LT	
					vitamin E (C)	26-DEC-1999	Pneumonia	H	
						26-DEC-1999	Respiratory distress	H, LT	
					vitamins (C)	26-DEC-1999	Pneumonia	H	
						26-DEC-1999	Respiratory distress	H, LT	
				0950	timolol maleate (C)	26-DEC-1999	Pneumonia	H	
						26-DEC-1999	Respiratory distress	H, LT	
					ascorbic acid (C)	26-DEC-1999	Pneumonia	H	
						26-DEC-1999	Respiratory distress	H, LT	
Product Name (Drug Type) 1) Placebo(S) - All 2) donepezil hydrochloride(C) 3) levothyroxine sodium(C) 4) diltiazem(C) 5) [therapy unspecified](C)									

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Case Number	Initial Receipt Date	Study ID	Patient Subject Report Type	Company Drug	Product Name	Onset Date	Preferred Term	Seriousness	Reported	
		Center ID	#	Code	(Drug Type)			Criteria	Causality	
			Randomization						Determined	
			Number						Causality	
			Observe Study							
			Type							
		6) calcium supplement (composition unspecified)(C)								
		7) vitamin E(C)								
		8) vitamins(C)								
		9) timolol maleate(C)								
		10) ascorbic acid(C)								
99123637	09-Dec-1999			Spontaneous	0950	timolol maleate (S)	1999	Eye pain	-	Unknown
Unknown										
Product Name (Drug Type) - All		1) timolol maleate(S)								
99123680	10-Dec-1999			Spontaneous	0950	timolol maleate (S)	1997	Drug hypersensitivity	-	Unknown
Unknown										
						1997	Eye pruritus	-	Unknown	
						1997	Conjunctivitis	-	Unknown	
Unknown										
Product Name (Drug Type) - All		1) timolol maleate(S)								
99124001	01-Dec-1999	0217-117	00017	Report From Study	Study Drug	alendronate sodium (S)	13-NOV-1999	Emphysema	H	Not Related
		0001	00017	Clinical Trial						Not Related
					9999	Placebo (C)	13-NOV-1999	Emphysema	H	
						doxazosin monomethanesulfonate (C)	13-NOV-1999	Emphysema	H	
					0507A	dorzolamide hydrochloride (+) timolol maleate (C)	13-NOV-1999	Emphysema	H	
						latanoprost (C)	13-NOV-1999	Emphysema	H	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					albuterol (+) ipratropium bromide (C)	13-NOV-1999	Emphysema	H	
Product Name (Drug Type) - All									
99125019	29-Nov-1999		Spontaneous	0950	timolol maleate (S)				1) alendronate sodium(S) 2) Placebo(C) 3) doxazosin monomethanesulfonate(C) 4) dorzolamide hydrochloride (+) timolol maleate(C) 5) latanoprost(C) 6) albuterol (+) ipratropium bromide(C)
						JUL-1999	Visual impairment	-	Unknown
									Not Assessed
						OCT-1999	Eye irritation	-	Related
									Related
					calcium acetylsalicylate (C)	JUL-1999	Eye discharge	-	Unknown
									Not Assessed
						OCT-1999	Eye pain	-	Related
									Related
						JUL-1999	Visual impairment	-	
						OCT-1999	Eye irritation	-	
					brimonidine D- tartrate (C)	JUL-1999	Eye discharge	-	
						OCT-1999	Eye pain	-	
					brimonidine D- tartrate (C)	JUL-1999	Visual impairment	-	
						OCT-1999	Eye irritation	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality					
					alginic acid (+) aluminum hydroxide (+) magnesium trisilicate (+) sodium bicarbonate (C)	JUL-1999	Eye discharge	-						
						OCT-1999	Eye pain	-						
						JUL-1999	Visual impairment	-						
						OCT-1999	Eye irritation	-						
						JUL-1999	Eye discharge	-						
						OCT-1999	Eye pain	-						
						Product Name (Drug Type) - All				1) timolol maleate(S) 2) calcium acetylsalicylate(C) 3) brimonidine D-tartrate(C) 4) alginic acid (+) aluminum hydroxide (+) magnesium trisilicate (+) sodium bicarbonate(C)				
						99125027	02-Dec-1999	Spontaneous	0950	timolol maleate (S)	02-NOV-1999	Heart rate decreased	H	Unknown
						1999	Heart rate decreased	-	Unknown					
						1999	Syncope	-	Unknown					
1999	Dizziness	-	Unknown											
02-NOV-1999	Syncope	H	Unknown											

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Product Name Code (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					02-NOV-1999	Dizziness	H	Unknown
								Unknown
				thyroxine (C)	02-NOV-1999	Heart rate decreased	H	
					1999	Heart rate decreased	-	
					1999	Syncope	-	
					1999	Dizziness	-	
					02-NOV-1999	Syncope	H	
					02-NOV-1999	Dizziness	H	
				bendroflumethia zide (C)	02-NOV-1999	Heart rate decreased	H	
					1999	Heart rate decreased	-	
					1999	Syncope	-	
					1999	Dizziness	-	
					02-NOV-1999	Syncope	H	
					02-NOV-1999	Dizziness	H	
Product Name (Drug Type) 1) timolol maleate(S) - All 2) thyroxine(C) 3) bendroflumethiazide(C)								

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
99125074	07-Dec-1999		Spontaneous	0950	timolol maleate (S)	SEP-1999	Eye pain	-	Related
Product Name (Drug Type) 1) timolol maleate(S) - All									Related
99125102	08-Dec-1999		Spontaneous	0950	timolol maleate (S)	AUG-1999	Conduction disorder	H	Unknown
									Unknown
						AUG-1999	Circulatory collapse	H	Unknown
									Unknown
						disopyramide (C)	AUG-1999	Conduction disorder	H
						AUG-1999	Circulatory collapse	H	
						aspirin (C)	AUG-1999	Conduction disorder	H
						AUG-1999	Circulatory collapse	H	
Product Name (Drug Type) 1) timolol maleate(S) - All 2) disopyramide(C) 3) aspirin(C)									
99125141	13-Dec-1999		Spontaneous	0966	rofecoxib (S)	06-DEC-1999	Syncope	H	Related
									Unknown
				0950	timolol maleate (C)	06-DEC-1999	Syncope	H	
						temazepam (C)	06-DEC-1999	Syncope	H
Product Name (Drug Type) 1) rofecoxib(S) - All 2) timolol maleate(C)									

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
3) temazepam(C)									
99125179	15-Dec-1999		Spontaneous	0950	timolol maleate (S)	10-DEC-1999	Eye pain	-	Related
					polyvinyl alcohol (C)	10-DEC-1999	Eye pain	-	Related
Product Name (Drug Type) 1) timolol maleate(S) - All 2) polyvinyl alcohol(C)									
99125207	20-Dec-1999		Spontaneous	0950	timolol maleate (S)		Conjunctival hyperaemia	-	Related
							Ocular discomfort	-	Related
							Rash	-	Related
							Eye pain	-	Unknown Not Assessed
									Related
					brimonidine D-tartrate (C)		Conjunctival hyperaemia	-	Related
							Ocular discomfort	-	
							Rash	-	
							Eye pain	-	
					bendroflumethia zide (C)		Conjunctival hyperaemia	-	
							Ocular discomfort	-	

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
							Rash	-	
							Eye pain	-	
					zopiclone (C)		Conjunctival hyperaemia	-	
							Ocular discomfort	-	
							Rash	-	
							Eye pain	-	
Product Name (Drug Type) 1) timolol maleate(S) - All 2) brimonidine D-tartrate(C) 3) bendroflumethiazide(C) 4) zopiclone(C)									
99125617	08-Dec-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)		Hypersensitivity	-	Related
									Related
Product Name (Drug Type) 1) dorzolamide hydrochloride (+) timolol maleate(S) - All									
99125632	13-Dec-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)		Visual field defect	-	Unknown
									Unknown
					latanoprost (C)		Visual field defect	-	
Product Name (Drug Type) 1) dorzolamide hydrochloride (+) timolol maleate(S)									

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
- All		2) latanoprost(C)							
99125662	06-Dec-1999		Spontaneous	0507	dorzolamide hydrochloride (S)		Maternal exposure timing unspecified	-	Not Related
							No adverse event	-	Not Related
				0950E	timolol maleate (+) pilocarpine hydrochloride (C)		Maternal exposure timing unspecified	-	Not Related
							No adverse event	-	Not Related
					latanoprost (C)		Maternal exposure timing unspecified	-	
							No adverse event	-	
Product Name (Drug Type)		1) dorzolamide hydrochloride(S) 2) timolol maleate (+) pilocarpine hydrochloride(C) 3) latanoprost(C)							
- All									
99126031	09-Dec-1999		Spontaneous	9337	aceclidine hydrochloride (S)	08-DEC-1999	Eye irritation	-	Related
						08-DEC-1999	Ocular hyperaemia	-	Related
					acebutolol hydrochloride	08-DEC-1999	Eye irritation	-	Related

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
					(C)				
						08-DEC-1999	Ocular hyperaemia	-	
					latanoprost (C)	08-DEC-1999	Eye irritation	-	
						08-DEC-1999	Ocular hyperaemia	-	
				0950	timolol maleate (C)	08-DEC-1999	Eye irritation	-	
						08-DEC-1999	Ocular hyperaemia	-	
				9334	acetazolamide (C)	08-DEC-1999	Eye irritation	-	
						08-DEC-1999	Ocular hyperaemia	-	
				9022	potassium chloride (C)	08-DEC-1999	Eye irritation	-	
						08-DEC-1999	Ocular hyperaemia	-	
Product Name (Drug Type) 1) aceclidine hydrochloride(S) - All 2) acebutolol hydrochloride(C) 3) latanoprost(C) 4) timolol maleate(C) 5) acetazolamide(C) 6) potassium chloride(C)									

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
99126121	23-Dec-1999		Spontaneous	0507	dorzolamide hydrochloride (S)	09-DEC-1999	Choroidal detachment	H	Related
						01-NOV-1999	Visual acuity reduced	H	Related
				0950	timolol maleate (C)	09-DEC-1999	Choroidal detachment	H	Related
						01-NOV-1999	Visual acuity reduced	H	Related
Product Name (Drug Type) 1) dorzolamide hydrochloride(S) - All 2) timolol maleate(C)									
99126133	17-Dec-1999		Spontaneous	0950	timolol maleate (S)	NOV-1999	Ear pain	-	Related
						DEC-1999	Ear pain	-	Related
				0507	dorzolamide hydrochloride (S)	NOV-1999	Ear pain	-	Not Related
						DEC-1999	Ear pain	-	Not Related
Product Name (Drug Type) 1) timolol maleate(S) - All 2) dorzolamide hydrochloride(S)									
99127932	07-Dec-1999		Spontaneous	0507	dorzolamide hydrochloride (S)	21-NOV-1999	Drug ineffective -	-	Related
				0950	timolol maleate (C)	21-NOV-1999	Drug ineffective -	-	Related

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Case Number	Initial Receipt Date	Study ID Center ID	Patient Subject Report Type # Randomization Observe Study Number Type	Company Drug Code	Product Name (Drug Type)	Onset Date	Preferred Term	Seriousness Criteria	Reported Causality Determined Causality
Product Name (Drug Type) 1) dorzolamide hydrochloride(S) - All 2) timolol maleate(C)									
99127938	07-Dec-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)		Eye irritation	-	Unknown
									Unknown
Product Name (Drug Type) 1) dorzolamide hydrochloride (+) timolol maleate(S) - All									
99128546	10-Dec-1999		Spontaneous	0507A	dorzolamide hydrochloride (+) timolol maleate (S)		Dizziness	-	Unknown
									Unknown
Product Name (Drug Type) 1) dorzolamide hydrochloride (+) timolol maleate(S) - All									

Total Row Count: 1072

Total Case Count: 98

Appendix

Section Title	Template Name	Query Name	Criteria
S3A001	Case Line Listing (Study)	None	

Report Legend

Column Name	Column Legend
Product Name (Drug Type)	S-Suspect, C-Concomitant, T-Treatment
Seriousness Criteria	D - Death, H - Hospitalization Required, CA - Congenital Anomaly, LT - Life Threatening, DIS - Disability, RI - Required Intervention, O - Other Medically Important Condition
Product Name (Drug Type) - All	S-Suspect, C-Concomitant, T-Treatment