



New Zealand Pharmacovigilance Centre

University of Otago
PO Box 913, Dunedin, New Zealand
Telephone: 64-3-479 7185
Fax: 64-3-479 7150
Email: nzphvc@otago.ac.nz
Website: www.otago.ac.nz/carm

Report Title: **Statin Adverse Reactions in the CARM database**

Prepared for: **OIA Request – Heather Barker**

Prepared by: **New Zealand Pharmacovigilance Centre
16 February 2015**

Period Covered: This search covers all spontaneous reports received by the Centre for Adverse Reactions Monitoring [CARM] from 01 January 2001 to 31 December 2014

Request Details: “...the number of adverse reactions to all brands of statins including fatalities in the period 2001 – 2014 or present date.”

“...breakdown of the type of adverse events.”

Summary: Statin medicines in New Zealand:
atorvastatin
fluvastatin
pravastatin
rosuvastatin
simvastatin

This document details 1709 reports describing 3826 reaction terms - one report may have more than one reaction described.

21 cases resulted in an outcome of death however in 3 cases death was not related to the Statin medicine and 2 cases were unclassifiable

Contents: Caveat Document
Reaction Listing



CAVEAT DOCUMENT

Accompanying statement to data released from the

NEW ZEALAND CENTRE FOR ADVERSE REACTIONS MONITORING

The Centre for Adverse Reactions Monitoring (CARM) has only limited details about each suspected adverse reaction contained in its Database. It is important that the limitations and qualifications which apply to the information and its use are understood.

The data made available represent the collection of spontaneous reports in the CARM database associated with therapeutic products/vaccines granted regulatory approval for use in New Zealand.

Reports have been submitted to the Centre since April 1965 and in many instances describe no more than suspicions which have arisen from observation of an unexpected or unwanted event. This level of reporting is due to CARM encouraging reporters to report events they suspect may be associated with a pharmaceutical product/vaccine irrespective of whether or not they believe it was the cause. CARM accepts all reports and proof of causality is not required when submitting a report to CARM. Coincidental events that may be unrelated to pharmaceutical product/vaccine exposure may be reported. This is particularly possible when the product has widespread use, or is used in targeted strategies such as vaccination campaigns.

In most instances it cannot be proven that a pharmaceutical product or ingredient is the cause of an event in the Database. Reports vary in quality, completeness and detail and may include detail that is incorrect. Consequently, a report in the CARM database of an event does not confirm that the pharmaceutical product/vaccine caused the event.

The volume of reports for a particular product may be influenced by the extent of use of the product, publicity, nature of reactions and other factors which vary over time and from product to product. It is generally accepted internationally that systems such as CARM are subject to underreporting which may result in scant reports for events perceived by the reporter to be minor or well recognised, whilst more serious or unexpected events are possibly more likely to be reported, even if they are coincidental. Moreover, no information is provided on the number of patients exposed to the product.

The data contained in these tables are further subject to ongoing internal quality controls, review and updating and therefore may be subject to change, particularly if follow-up information is received.

For the above reasons interpretations of adverse reaction data, and particularly those based on comparisons between pharmaceutical products, may be misleading. Any use of this information must take into account at least the above. Although this information is now released, it is strongly recommended that prior to any use of such information, CARM is contacted for interpretation.

Any publication, in whole or in part, of the obtained information must have published with it a statement:

- (i) of the source of the information
- (ii) that the information is not homogenous at least with respect to origin or likelihood that the pharmaceutical product/vaccine caused the adverse reaction
- (iii) that the information does not represent the opinion of the NZPhvC or CARM.

Director
New Zealand Pharmacovigilance Centre



Medicines:

In the period 01 January 2001 through to 31 December 2014 the following reports were received:

Atorvastatin	415
Fluvastatin	3
Pravastatin	11
Rosuvastatin	19
Simvastatin	1261

Reports:

The breakdown per year was:

Year	Atorvastatin	Fluvastatin	Pravastatin	Rosuvastatin	Simvastatin	Total
2001	25	3			13	41
2002	23				56	79
2003	9				73	82
2004	14				143	157
2005	9				166	175
2006	7				205	212
2007	18				103	121
2008	15				85	100
2009	20			2	190	212
2010	22				59	81
2011	46			4	33	83
2012	87		2	5	51	145
2013	63		6	3	37	109
2014	57		3	5	47	112
Total	415	3	11	19	1261	1709

Fatalities:

Analysis of 21 cases resulting in death

Outcome	Atorvastatin	Simvastatin	Total
Died due to the adverse reaction		7	7
Died medicine may be contributory	2	7	9
Died – cause unclassifiable		2	2
Died – unrelated to medicine	3		3

Reactions:

Details of the individual reaction terms and the number of times each term occurs are collated within clinical groupings in the attached listing:

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
Alimentary	ABDOMEN ENLARGED	1				1	2
	ABDOMINAL DISTENSION					3	3
	ABDOMINAL PAIN	13			1	50	64
	AGEUSIA					2	2
	ANOREXIA	1				4	5
	APPETITE DECREASED					1	1
	APPETITE INCREASED					1	1
	BLOATING	1				5	6
	BOWEL MOTILITY DISORDER					1	1
	BURNING SENSATION	1					1
	CHANGE IN BOWEL HABITS					2	2
	CHEILITIS					2	2
	CHOLECYSTITIS	1					1
	CHOLELITHIASIS	2				1	3
	COLIC ABDOMINAL					1	1
	COLITIS					1	1
	CONSTIPATION	5		1		22	28
	CRAMP ABDOMINAL					1	1
	DIARRHOEA	7			1	41	49
	DYSPEPSIA	2		1		22	25
	DYSPHAGIA	2				3	5
	ERUCTATION					4	4
	FAECAL INCONTINENCE					3	3
	FLATULENCE	2				16	18
	GASTRIC ULCER					2	2
	GASTRIC ULCER HAEMORRHAGIC					1	1
	GASTRO-INTESTINAL DISORDER NOS	3					3
	GASTROENTERITIS					1	1
	GASTROESOPHAGEAL REFLUX	1				4	5
	GINGIVITIS	2					2
	GLOSSITIS	2					2

(Continued)

Statins

		Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
RGROUP	reaction						
Alimentary	HAEMORRHAGE RECTUM					1	1
	HAEMORRHOIDS					1	1
	IRRITABLE BOWEL SYNDROME					1	1
	LIP DISORDER	1					1
	MELAENA	1					1
	MOUTH DRY	3				7	10
	NAUSEA	17		1	1	60	79
	PANCREAS NEOPLASM MALIGNANT	1					1
	PROCTALGIA					2	2
	RECTAL BLEEDING					3	3
	RECTAL DISORDER	1					1
	STOMATITIS					3	3
	STOMATITIS ULCERATIVE					2	2
	THROAT DRY					2	2
	TONGUE DISCOLOURATION					1	1
	TONGUE GEOGRAPHIC					1	1
	TONGUE PAIN	1				3	4
	TONGUE ULCERATION					1	1
	TOOTH ABSCESS					1	1
	TOOTH ACHE					2	2
TOOTH DISCOLOURATION					1	1	
VOMITING	2			1	23	26	
*** Total for Group ***		73		3	4	310	390
Application Site	reaction						
	LIPODYSTROPHY					1	1
	*** Total for Group ***						1
Cardiovascular	reaction						
	ANGINA PECTORIS					1	1
	ANGINA PECTORIS AGGRAVATED	2					2
	ARRHYTHMIA					2	2
	ATRIAL FIBRILLATION					1	1

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
Cardiovascular	BRADYCARDIA	1				1	2
	CARDIAC ARREST	2				1	3
	CARDIAC FAILURE					4	4
	CARDIOMYOPATHY					1	1
	CARDIOVASCULAR DISORDERS					1	1
	CHEST DISCOMFORT	2					2
	CHEST PAIN	6			1	19	26
	CHEST TIGHTNESS	2				2	4
	COLLAPSE CIRCULATORY	1					1
	CONGESTIVE HEART FAILURE					1	1
	DIZZINESS	7		2	2	53	64
	ECG ABNORMAL	1					1
	FAINTNESS	1					1
	FLUSHING	1				5	6
	HEART DISORDER	1					1
	HYPERTENSION	1				4	5
	HYPERTENSION AGGRAVATED					2	2
	HYPOTENSION	3			1	4	8
	HYPOTENSION POSTURAL	2					2
	MYOCARDIAL INFARCTION	2					2
	MYOCARDITIS					1	1
	PALPITATION	4				11	15
	PERIPHERAL COLDNESS	1					1
	PERIPHERAL ISCHAEMIA	1					1
	SYNCOPE	1				6	7
	TACHYCARDIA	1				1	2
	TACHYCARDIA VENTRICULAR	1					1
	THROMBOPHLEBITIS SUPERFICIAL					1	1
	THROMBOSIS ARTERIAL					1	1
	VASCULITIS					2	2
	VASOCONSTRICTION	1					1

(Continued)

Statins

		Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
RGROUP	reaction						
Cardiovascular	VASODILATION					1	1
	VEIN DISTENDED					1	1
	*** Total for Group ***	45		2	4	127	178
Collagen Disorders	reaction						
	ANTINUCLEAR FACTOR TEST POSITIVE	2				1	3
	*** Total for Group ***	2				1	3
Endocrine/Metabolic	reaction						
	AMYLASE INCREASED					3	3
	BREAST ENLARGEMENT					1	1
	BREAST ENLARGEMENT MALE					2	2
	CREATINE PHOSPHOKINASE INCREASED	25			1	94	120
	CREATININE BLOOD INCREASED					2	2
	DEHYDRATION	1				1	2
	DIABETES MELLITUS	3				1	4
	DIABETES MELLITUS AGGRAVATED	4				1	5
	DIABETES MELLITUS NIDDM	2					2
	DIABETIC KETOACIDOSIS					1	1
	ELECTROLYTE ABNORMALITY	1					1
	ERECTILE DYSFUNCTION					2	2
	FAT ATROPHY					2	2
	GOUT					2	2
	GOUT AGGRAVATED					2	2
	GYNAECOMASTIA	3				5	8
	HDL DECREASED	1				1	2
	HYPERCHOLESTEROLAEMIA					1	1
	HYPERGLYCAEMIA	1				4	5
	HYPERKALAEMIA					3	3
	HYPERTRIGLYCERIDAEMIA	1					1
	HYPOGLYCAEMIA	1			1	2	4
HYPOKALAEMIA					1	1	
HYPOMAGNEAEMIA					1	1	

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
Endocrine/Metabolic	IMPOTENCE	2				7	9
	LDH INCREASED					1	1
	MYOGLOBINURIA					1	1
	PANCREATITIS	2				11	13
	PEYRONIES DISEASE					1	1
	PLASMA OSMOLALITY INCREASED					1	1
	POLYDIPSIA					1	1
	SERUM FERRITIN INCREASED	1					1
	TESTOSTERONE DECREASED					1	1
	THIRST					2	2
	THYROID DISORDER					2	2
	TROPONIN T INCREASED					2	2
	WEIGHT DECREASE	4				7	11
	WEIGHT INCREASE	2				5	7
	*** Total for Group ***	54			2	174	230
Foetal Disorders	reaction						
	FOETAL DISORDERS	1					1
	*** Total for Group ***	1					1
Haematological	reaction						
	ANAEMIA	3				3	6
	ANAEMIA APLASTIC					1	1
	ANAEMIA HAEMOLYTIC					1	1
	C-REACTIVE PROTEIN POSITIVE	2				5	7
	DISSEM. INTRAVASC. COAGULATION					1	1
	EOSINOPHILIA					1	1
	EPISTAXIS	2				7	9
	ESR INCREASED	1				1	2
	HAEMORRHAGE NOS	1					1
	INR DECREASED	1					1
	INR INCREASED	1				2	3
	LEUKOCYTOSIS					2	2

(Continued)

Statins

		Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
RGROUP	reaction						
Haematological	LYMPHADENOPATHY					1	1
	THROMBOCYTOPENIA	1	1		1		3
	THROMBOCYTOSIS					1	1
	*** Total for Group ***	12	1		1	26	40
Liver	reaction						
	BILIRUBINAEMIA	2				1	3
	BILIRUBINURIA	1					1
	HEPATIC CIRRHOSIS					1	1
	HEPATIC CYST					1	1
	HEPATIC ENZYMES INCREASED	33				46	79
	HEPATIC FAILURE					3	3
	HEPATIC FUNCTION ABNORMAL	8				14	22
	HEPATIC NEOPLASM MALIGNANT	1					1
	HEPATITIS	3				4	7
	HEPATITIS CHOLESTATIC	3				4	7
	HEPATITIS VIRAL	1					1
	HEPATOCELLULAR DAMAGE	3				8	11
	HEPATOMEGALY					2	2
	HYPERBILIRUBINAEMIA					1	1
	JAUNDICE	3				9	12
	LIVER FATTY	1				1	2
	SGOT INCREASED					1	1
*** Total for Group ***	59				96	155	
Musculoskeletal	reaction						
	ARTHRALGIA	24			1	81	106
	ARTHRITIS	2			2	7	11
	ARTHRITIS AGGRAVATED	2					2
	ARTHRITIS RHEUMATOID	1				2	3
	ARTHROPATHY	1				1	2
	BACK PAIN	6				31	37
	BONE DISORDER					1	1

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
Musculoskeletal	BURSITIS	2					2
	CALF PAIN	1					1
	CRAMPS	8				31	39
	CRAMPS LEGS	1				11	12
	FASCITIS PLANTAR					1	1
	JAW PAIN					3	3
	JOINT EFFUSION					1	1
	JOINT PAIN					1	1
	JOINT STIFFNESS	2				3	5
	JOINT SWELLING NON-INFLAMMATORY	1				2	3
	LEG PAIN	4				14	18
	LUMBAR DISC LESION					1	1
	MOVEMENTS REDUCED				1	1	2
	MUSCLE ATROPHY	2					2
	MUSCLE PAIN	1				2	3
	MUSCLE SPASTICITY					1	1
	MUSCLE STIFFNESS	3				5	8
	MUSCLE WASTING					4	4
	MUSCLE WEAKNESS	65		2	5	103	175
	MUSCULOSKELETAL DISORDER	1					1
	MUSCULOSKELETAL PAIN	1				2	3
	MYALGIA	90	1	1	4	311	407
	MYOPATHY	5				33	38
	MYOSITIS	7				16	23
	NECK STIFFNESS	1					1
	PAIN IN LIMB					15	15
	PAIN NECK/SHOULDER	3				14	17
	POLYMYOSITIS					1	1
	RHABDOMYOLYSIS	5	1			49	55
	SKELETAL PAIN	2				13	15
	SYNOVITIS	1				4	5

(Continued)

Statins

		Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
RGROUP	reaction						
Musculoskeletal	TENDINITIS	2				1	3
	TENDON DISORDER					2	2
	*** Total for Group ***	244	2	3	13	768	1030
Nervous System	reaction						
	ATAXIA	1				21	22
	BURNING SKIN			1			1
	CEREBROVASCULAR DISORDER	1					1
	COGNITIVE FUNCTION ABNORMAL	1				1	2
	CONVULSIONS					1	1
	CONVULSIONS AGGRAVATED	1					1
	COORDINATION ABNORMAL					2	2
	DROWSINESS					1	1
	DYSAESTHESIA	9				16	25
	DYSKINESIA					1	1
	ELECTRIC SHOCK SENSATION	1					1
	EXTRAPYRAMIDAL DISORDER					1	1
	FORMICATION	1			1	1	3
	HEADACHE	23			2	83	108
	HEADACHE VASOMOTOR					1	1
	HYPERAESTHESIA					1	1
	HYPERKINESIA					5	5
	HYPERTONIA	1				7	8
	HYPOAESTHESIA	2				12	14
	HYPOTONIA					1	1
	LIMB WEAKNESS					1	1
	MIGRAINE					3	3
MOBILITY DECREASED					1	1	
MONONEURITIS					2	2	
MONOPLÉGIA	1					1	
MUSCLE CONTRACTIONS INVOLUNTARY	1				9	10	
NERVE ROOT LESION					1	1	

(Continued)

Statins

		Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
RGROUP	reaction						
Nervous System	NEURITIS SENSORY					1	1
	NEUROMYOPATHY					1	1
	NEUROPATHY					4	4
	NEUROPATHY PERIPHERAL	7				12	19
	NUMBNESS LOCALISED	1				5	6
	OCULOGYRIC CRISIS					1	1
	PAIN	3				6	9
	PAIN GROIN					1	1
	PAIN IN FACE					1	1
	PARAESTHESIA	4		2	1	36	43
	PARAESTHESIA DISTAL	7				4	11
	PARAESTHESIA MOUTH					2	2
	PARAESTHESIA TONGUE					1	1
	PARALYSIS					1	1
	PERIPHERAL NEURITIS					1	1
	POLYNEUROPATHY	1					1
	RESTLESS LEGS					1	1
	SHAKING					2	2
	SOMNAMBULISM					1	1
	SPASM GENERALISED					1	1
	SPEECH DISORDER					1	1
	TRANSIENT ISCHAEMIC ATTACK					1	1
	TREMOR	3				4	7
URINARY INCONTINENCE					1	1	
VERTIGO	4				7	11	
*** Total for Group ***		73		3	4	268	348
Others	reaction						
	ACCIDENT	2			1	2	5
	ALCOHOL INTOLERANCE					1	1
	ALLERGIC REACTION	1				1	2
	ANAPHYLACTIC REACTION	1					1

(Continued)

Statins

		Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
RGROUP	reaction						
Others	ANAPHYLACTOID REACTION	1					1
	BLOOD ALCOHOL EXCESSIVE					1	1
	CHILLS	1					1
	DRESS SYNDROME	1					1
	DRUG - ALCOHOL INTERACTION					1	1
	DRUG - FOOD INTERACTION	1				2	3
	DRUG INTERACTION	12				69	81
	FACE OEDEMA	1				5	6
	FALL	3				9	12
	FEELING COLD					2	2
	FEELING OF WARMTH					3	3
	FEVER	5				5	10
	HOT FLUSHES					1	1
	INFLUENZA-LIKE SYMPTOMS	2			1	6	9
	LIPS SWELLING NON-SPECIFIC					2	2
	NIGHT SWEATS	2				1	3
	OEDEMA					3	3
	OEDEMA LEGS	1				6	7
	OEDEMA MOUTH	1				3	4
	OEDEMA PERIORBITAL	2				3	5
	OEDEMA PERIPHERAL	3				10	13
	PAIN TRAUMA ACTIVATED					1	1
	PALLOR					1	1
	POLYMYALGIA RHEUMATICA	1				1	2
	POLYMYALGIA RHEUMATICA AGGRAVATED	1					1
	PRIAPISM	1				1	2
	RIGORS					1	1
	SNORING					1	1
	SUDDEN DEATH					1	1
	SWEATING INCREASED					5	5
TEMPERATURE CHANGED SENSATION	1				2	3	

(Continued)

Statins

		Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
RGROUP	reaction						
Others	THERAPEUTIC RESPONSE DECREASED					8	8
	THROAT SWELLING NON-SPECIFIC	1				3	4
	TONGUE OEDEMA	2				6	8
	TONGUE SWELLING NON-SPECIFIC					1	1
	UNEXPECTED THERAPEUTIC EFFECT					1	1
	*** Total for Group ***	47			2	169	218
Procedure Related	reaction						
	ACCIDENTAL OVERDOSE					1	1
	MEDICATION ERROR					18	18
	*** Total for Group ***					19	19
Product Related	reaction						
	BRAND SWITCH	36				144	180
	GENERIC SWITCH	9				10	19
	PRODUCT FORMULATION CHANGE	13				1	14
	PRODUCT STORAGE ERROR	1					1
	*** Total for Group ***	59				155	214
Psychiatric Changes	reaction						
	AGGRESSIVE REACTION	3				4	7
	AGITATION					2	2
	AMNESIA	12				27	39
	ANGER					2	2
	ANXIETY	1				6	7
	ASTHENIA	1				11	12
	BEHAVIOUR ABNORMAL					1	1
	COGNITIVE DETERIORATION					2	2
	CONCENTRATION IMPAIRED	3		1	2	6	12
	CONFUSION	8				15	23
	DEMENTIA	1					1
	DEPERSONALIZATION	2			1	3	6
	DEPRESSION	11		1		30	42
DISORIENTATION	2				4	6	

(Continued)

Statins

		Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
RGROUP	reaction						
Psychiatric Changes	DREAMING ABNORMAL				1	8	9
	EMOTIONAL LABILITY	1		1		4	6
	FATIGUE	17			1	31	49
	HALLUCINATION	2				6	8
	HALLUCINATION AUDITORY					1	1
	HALLUCINATION VISUAL	1					1
	INSOMNIA	10				16	26
	IRRITABILITY	1				3	4
	LETHARGY	11				42	53
	MALaise	9			2	18	29
	MEMORY DISTURBANCE			1			1
	MEMORY IMPAIRMENT	10				16	26
	MEMORY LOSS	11				11	22
	MOOD DISORDER	1				1	2
	NERVOUSNESS					1	1
	PANIC REACTION					1	1
	PARANOID REACTION	1					1
	PARONIRIA	1		2		12	15
	PERSONALITY DISORDER					2	2
	SLEEP DISORDER				1	2	3
	SLEEP DISTURBED	1				7	8
	SOMNOLENCE	2				8	10
	SUICIDAL TENDENCY					4	4
	SUICIDE					1	1
SUICIDE ATTEMPT					1	1	
THINKING ABNORMAL					3	3	
TIREDNESS	3				22	25	
*** Total for Group ***		126		6	8	334	474
Reproductive Disorders	reaction						
	BREAST PAIN					1	1
	BREAST PAIN FEMALE	1				1	2

(Continued)

Statins

		Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
RGROUP	reaction						
Reproductive Disorders	BREAST PAIN MALE					4	4
	BREAST TENDERNESS	1					1
	GENITAL ULCERATION					1	1
	LIBIDO DECREASED	2				3	5
	*** Total for Group ***	4				10	14
Resistance Mechanism Disorders	reaction						
	ABSCESS					1	1
	ANTIBODIES DRUG SPECIFIC	1					1
	CELLULITIS	1					1
	SEPSIS					1	1
	*** Total for Group ***	2				2	4
Respiratory	reaction						
	BRONCHITIS					1	1
	BRONCHOSPASM					1	1
	BRONCHOSPASM AGGRAVATED	2					2
	CORYZA					1	1
	COUGHING	3				13	16
	DYSPNOEA	6				30	36
	HOARSENESS	1					1
	INTERSTITIAL LUNG DISEASE					1	1
	NASAL CONGESTION	1					1
	NASAL DRYNESS					1	1
	PHARYNGITIS	1				1	2
	PNEUMONIA	1				3	4
	PNEUMONIA INTERSTITIAL					1	1
	PULMONARY DISORDERS					1	1
	PULMONARY FIBROSIS	1					1
	PULMONARY OEDEMA					1	1
	RESPIRATORY DISORDER					1	1
RESPIRATORY FAILURE					1	1	
RHINITIS	1				2	3	

(Continued)

Statins

		Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
RGROUP	reaction						
Respiratory	SINUSITIS	1				1	2
	THROAT IRRITATION	1				1	2
	THROAT TIGHTNESS					6	6
	*** Total for Group ***	19				67	86
Skin and Appendages	reaction						
	ALOPECIA	5				34	39
	ALOPECIA AREATA					1	1
	ANGIOEDEMA	3		1		8	12
	BULLOUS ERUPTION	1				4	5
	DERMATITIS	2				2	4
	DERMATITIS EXFOLIATIVE					1	1
	DERMATITIS LICHENOID	1					1
	ECZEMA	2				3	5
	ERYTHEMA	3					3
	ERYTHEMA MULTIFORME	1				2	3
	ERYTHRODERMA	1					1
	HAIR DISORDER NOS					1	1
	HAIR LOSS	4		1		4	9
	HAIR TEXTURE ABNORMAL	1				1	2
	HAIR THINNING				1		1
	HERPES SIMPLEX	1					1
	LE SYNDROME	1				1	2
	LUPUS ERYTHEMATOSUS SYSTEMIC	1					1
	MACULAR RASH	1					1
	NAIL DISORDER					1	1
	PEMPHIGOID REACTION					1	1
	PHOTOSENSITIVITY REACTION	1				6	7
PRURITUS	9				27	36	
PRURITUS ANI	1					1	
PSORIASIS AGGRAVATED					1	1	
PURPURA					5	5	

(Continued)

Statins

		Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
RGROUP	reaction						
Skin and Appendages	RASH	12				27	39
	RASH ERYTHEMATOUS	3				6	9
	RASH MACULO-PAPULAR	2				2	4
	RASH PETECHIAL					1	1
	RASH PRURITIC	6				21	27
	RASH PURPURIC					1	1
	RASH PUSTULAR					2	2
	SCAR					1	1
	SKIN DISCOLOURATION					1	1
	SKIN DISORDER	1					1
	SKIN DRY	1					1
	SKIN EXFOLIATION					1	1
	SKIN IRRITATION	1				1	2
	SKIN NODULE					1	1
	SKIN ULCERATION					1	1
	TOXIC EPIDERMAL NECROLYSIS	1					1
	URTICARIA	6			1	19	26
	VESICULAR RASH					1	1
	*** Total for Group ***		72		2	2	189
Special Senses	reaction						
	ANOSMIA	1				4	5
	CATARACT					1	1
	CHROMATOPSIA	1					1
	CONJUNCTIVITIS	2				4	6
	DIPLOPIA					4	4
	DRY EYES					1	1
	DYSGEUSIA	1				3	4
	EYE PAIN					1	1
	GLAUCOMA					1	1
	HEARING IMPAIRED					1	1
	KERATOCONJUNCTIVITIS					1	1

(Continued)

Statins

		Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
RGROUP	reaction						
Special Senses	LACRIMATION ABNORMAL	1				3	4
	OCULAR HAEMORRHAGE					1	1
	PAROSMIA					1	1
	PHOTOPHOBIA	1					1
	TASTE LOSS	2				1	3
	TASTE METALLIC	1				4	5
	TASTE PERVERSION	2				3	5
	TINNITUS	1		1	1	4	7
	TINNITUS AGGRAVATED					1	1
	UVEITIS					1	1
	VISION ABNORMAL					8	8
	VISION BLURRED					8	8
	VISION DECREASED	1					1
	XEROPHTHALMIA					3	3
	*** Total for Group ***		14		1	1	59
Urinary	reaction						
	ANURIA					1	1
	DYSURIA			1		1	2
	ENURESIS					1	1
	HAEMATURIA					5	5
	HYDRONEPHROSIS	1					1
	KIDNEY CONTRACTED					1	1
	MICTURITION DISORDER					2	2
	MICTURITION FREQUENCY	2		2		4	8
	NOCTURIA	2				2	4
	NOCTURIA AGGRAVATED					1	1
	OLIGURIA					2	2
	POLYURIA	2					2
	RENAL FAILURE ACUTE	1				25	26
	RENAL FAILURE AGGRAVATED					3	3
RENAL FAILURE NOS					3	3	

Statins

		Medicine					Total
		ATORVAS-TATIN	FLUVAST-ATIN	PRAVAST-ATIN	ROSUVAS-TATIN	SIMVAST-ATIN	
		N	N	N	N	N	
RGROUP	reaction						
Urinary	RENAL FUNCTION ABNORMAL	1				4	5
	RENAL PAIN					3	3
	RETROPERITONEAL FIBROSIS	1					1
	URINE ABNORMAL					3	3
	URINE DISCOLOURATION	3				1	4
	URINE FLOW DECREASED	1					1
	URINE ODOUR FOUL	1				1	2
	*** Total for Group ***	15		3		63	81
Total Reactions		921	3	23	42	2837	3826