



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



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

Medicines:

In the period 01 January 2001 through to 31 December 2015 the following reports were received:

Atorvastatin	453
Fluvastatin	3
Pravastatin	14
Rosuvastatin	24
Simvastatin	1283

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
2015	38		3	5	22	68
Total	453	3	14	24	1283	1777

Fatalities:

Analysis of 23 cases resulting in death

Outcome	Atorvastatin	Rosuvastatin	Simvastatin	Total
Died due to the adverse reaction			7	7
Died medicine may be contributory	3	1	7	11
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-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Alimentary	ABDOMEN ENLARGED	1				1	2
	ABDOMINAL DISTENSION					3	3
	ABDOMINAL PAIN	14			1	50	65
	AGEUSIA					2	2
	ANOREXIA	1				4	5
	APPETITE DECREASED					1	1
	APPETITE INCREASED					1	1
	BLOATING	2				5	7
	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
	FAECAL OCCULT BLOOD POSITIVE	1					1
	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

(Continued)

Statins

RGROUP	reaction	Medicine					Total	
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-		
		TATIN	ATIN	ATIN	TATIN	ATIN		
		N	N	N	N	N	N	
Alimentary	GLOSSITIS	2					2	
	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	61	80	
	ORAL MUCOSA BLISTERING	1					1	
	PANCREAS NEOPLASM MALIGNANT	1					1	
	PROCTALGIA					2	2	
	RECTAL BLEEDING	1				3	4	
	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 ***		78		3	4	311	396
	Application Site	reaction						
		LIPODYSTROPHY					1	1
*** Total for Group ***						1	1	
Cardiovascular	reaction							
	ANGINA PECTORIS					1	1	
	ANGINA PECTORIS AGGRAVATED	2					2	

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Cardiovascular	ARRHYTHMIA					2	2
	ATRIAL FIBRILLATION					1	1
	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	7			1	19	27
	CHEST TIGHTNESS	2				2	4
	COLLAPSE CIRCULATORY	1					1
	CONGESTIVE HEART FAILURE					1	1
	DIZZINESS	8		2	2	53	65
	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	5	9
	HYPOTENSION POSTURAL	2					2
	MYOCARDIAL INFARCTION	2					2
	MYOCARDITIS					1	1
	PALPITATION	5				11	16
	PERIPHERAL COLDNESS	1					1
	PERIPHERAL ISCHAEMIA	1					1
	PERIPHERAL VASOCONSTRICTION	1					1
	SYNCOPE	1				6	7
	TACHYCARDIA	1				1	2
	TACHYCARDIA VENTRICULAR	1					1
	THROMBOPHLEBITIS SUPERFICIAL					1	1

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Cardiovascular	THROMBOSIS ARTERIAL					1	1
	VASCULITIS					2	2
	VASOCONSTRICTION	1					1
	VASODILATION					1	1
	VEIN DISTENDED					1	1
	*** Total for Group ***	49		2	4	128	183
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	28			1	95	124
	CREATININE BLOOD INCREASED					2	2
	DEHYDRATION	1				1	2
	DIABETES MELLITUS	3				2	5
	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
	GOITRE	1					1
	GOUT					2	2
	GOUT AGGRAVATED					3	3
	GYNAECOMASTIA	3		1		6	10
	HDL DECREASED	1				1	2
	HYPERCHOLESTEROLAEMIA					1	1
	HYPERGLYCAEMIA	1				4	5
	HYPERKALAEMIA					3	3

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Endocrine/Metabolic	HYPERTRIGLYCERIDAEMIA	1					1
	HYPOGLYCAEMIA	1			1	2	4
	HYPOKALAEMIA					1	1
	HYPOMAGNEAEMIA					1	1
	IMPOTENCE	2				7	9
	LDH INCREASED					1	1
	MYOGLOBINURIA					1	1
	PANCREATITIS	3				11	14
	PEYRONIES DISEASE					1	1
	PLASMA OSMOLALITY INCREASED					1	1
	POLYDIPSIA					1	1
	SERUM FERRITIN INCREASED	1					1
	TESTOSTERONE DECREASED			1		1	2
	THIRST					2	2
	THYROID DISORDER					2	2
	TROPONIN T INCREASED					2	2
	WEIGHT DECREASE	5				7	12
	WEIGHT INCREASE	2				5	7
	*** Total for Group ***	60		2	2	178	242
Foetal Disorders	reaction						
	FOETAL DISORDERS	1					1
	*** Total for Group ***	1					1
Haematological	reaction						
	ANAEMIA	4				3	7
	ANAEMIA APLASTIC					1	1
	ANAEMIA HAEMOLYTIC					1	1
	C-REACTIVE PROTEIN POSITIVE	2				5	7
	DISSEM. INTRAVASC. COAGULATION					1	1
	EOSINOPHILIA					1	1
	EPISTAXIS	3				7	10
	ESR INCREASED	1				1	2

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Haematological	HAEMORRHAGE NOS	2					2
	INR DECREASED	1					1
	INR INCREASED	1				3	4
	LEUKOCYTOSIS					2	2
	LYMPHADENOPATHY					1	1
	THROMBOCYTOPENIA	1	1		1		3
	THROMBOCYTOSIS					1	1
	*** Total for Group ***	15	1		1	27	44
Liver	BILIRUBINAEMIA	2				1	3
	BILIRUBINURIA	1					1
	HEPATIC CIRRHOSIS					1	1
	HEPATIC CYST					1	1
	HEPATIC ENZYMES INCREASED	37				48	85
	HEPATIC FAILURE					3	3
	HEPATIC FUNCTION ABNORMAL	8				14	22
	HEPATIC NEOPLASM MALIGNANT	1					1
	HEPATITIS	3				4	7
	HEPATITIS CHOLESTATIC	4				4	8
	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 ***	64				98	162
Musculoskeletal	ARTHRALGIA	24			1	82	107
	ARTHRITIS	2			3	7	12
	ARTHRITIS AGGRAVATED	2					2

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Musculoskeletal	ARTHRITIS RHEUMATOID	1				2	3
	ARTHROPATHY	1				1	2
	BACK PAIN	6				31	37
	BONE DISORDER					1	1
	BURSITIS	2					2
	CALF PAIN	1					1
	CRAMPS	9				31	40
	CRAMPS LEGS	1				11	12
	FASCITIS PLANTAR					1	1
	FRACTURE PATHOLOGICAL	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	75		2	8	115	200
	MUSCULOSKELETAL DISORDER	1					1
	MUSCULOSKELETAL PAIN	1				2	3
	MYALGIA	100	1	1	7	319	428
	MYOPATHY	8				33	41
	MYOSITIS	9				16	25
	NECK STIFFNESS	1					1
	PAIN IN LIMB					15	15

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Musculoskeletal	PAIN NECK/SHOULDER	3				14	17
	POLYMYOSITIS					1	1
	RHABDOMYOLYSIS	6	1			51	58
	SKELETAL PAIN	2				13	15
	SYNOVITIS	1				4	5
	TENDINITIS	2				1	3
	TENDON DISORDER					2	2
	*** Total for Group ***	272	2	3	20	791	1088
Nervous System	reaction						
	ATAXIA	2				21	23
	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	84	109
	HEADACHE VASOMOTOR					1	1
	HYPERAESTHESIA					1	1
	HYPERKINESIA					5	5
	HYPERTONIA	1				7	8
	HYPOAESTHESIA	2				13	15
	HYPOTONIA					1	1
	LIMB WEAKNESS					1	1
	MIGRAINE					3	3

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Nervous System	MOBILITY DECREASED					4	4
	MONONEURITIS					2	2
	MONOPLÉGIA	1					1
	MUSCLE CONTRACTIONS INVOLUNTARY	1				9	10
	MYOCLONIC JERKS	1					1
	NERVE ROOT LESION					1	1
	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				6	13
	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

(Continued)

Statins

RGROUP	*** Total for Group ***	Medicine					Total
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Nervous System		75		3	4	275	357
Others	reaction						
	ACCIDENT	2			1	4	7
	ALCOHOL INTOLERANCE					1	1
	ALLERGIC REACTION	1				2	3
	ANAPHYLACTIC REACTION	1					1
	ANAPHYLACTOID REACTION	1					1
	BLOOD ALCOHOL EXCESSIVE					1	1
	BONE METASTASES	1					1
	CHILLS	1					1
	DRESS SYNDROME	1					1
	DRUG - ALCOHOL INTERACTION					1	1
	DRUG - FOOD INTERACTION	1				3	4
	DRUG INTERACTION	14				71	85
	FACE OEDEMA	1				6	7
	FALL	3				9	12
	FEELING COLD					2	2
	FEELING OF WARMTH					3	3
	FEVER	6				5	11
	HOT FLUSHES					1	1
	INFLUENZA-LIKE SYMPTOMS	2			1	6	9
	LIPS SWELLING NON-SPECIFIC					2	2
	METASTASES NOS	2					2
	MULTIPLE ORGAN FAILURE	1					1
	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

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Others	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
	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 ***	54			2	176	232
Procedure Related	reaction						
	ACCIDENTAL OVERDOSE					1	1
	MEDICATION ERROR	2				18	20
	*** Total for Group ***	2				19	21
Product Related	reaction						
	BRAND SWITCH	37				144	181
	GENERIC SWITCH	9				10	19
	PRODUCT FORMULATION CHANGE	13				1	14
	PRODUCT STORAGE ERROR	1					1
	*** Total for Group ***	60				155	215
Psychiatric Changes	reaction						
	AGGRESSIVE REACTION	3				4	7
	AGITATION					2	2
	AMNESIA	12				27	39
	ANGER					2	2
	ANXIETY	1				6	7

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Psychiatric Changes	ASTHENIA	1				12	13
	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		31	43
	DISORIENTATION	2				4	6
	DREAMING ABNORMAL				1	8	9
	EMOTIONAL LABILITY	1		2		4	7
	FATIGUE	19			1	31	51
	HALLUCINATION	2				6	8
	HALLUCINATION AUDITORY					1	1
	HALLUCINATION VISUAL	1					1
	INSOMNIA	10				16	26
	IRRITABILITY	1		1		3	5
	LETHARGY	13				43	56
	MALAISE	9			2	18	29
	MEMORY DISTURBANCE			1			1
	MEMORY IMPAIRMENT	11				17	28
	MEMORY LOSS	11				13	24
	MOOD DISORDER	1				1	2
	NERVOUSNESS					1	1
	PANIC REACTION					1	1
	PARANOID REACTION	1					1
	PARONIRIA	2		2		12	16
	PERSONALITY DISORDER					2	2
	SLEEP DISORDER				1	2	3
	SLEEP DISTURBED	2				7	9
	SOMNOLENCE	2				8	10

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Psychiatric Changes	SUICIDAL TENDENCY					4	4
	SUICIDE					1	1
	SUICIDE ATTEMPT					1	1
	THINKING ABNORMAL					3	3
	TIREDNESS	3				22	25
	*** Total for Group ***	133		8	8	340	489
Reproductive Disorders	BREAST PAIN					1	1
	BREAST PAIN FEMALE	1				1	2
	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	ABSCCESS					1	1
	ANTIBODIES DRUG SPECIFIC	3					3
	CANDIDIASIS	1					1
	CELLULITIS	1					1
	SEPSIS					1	1
	*** Total for Group ***	5				2	7
Respiratory	BRONCHITIS					1	1
	BRONCHOSPASM					1	1
	BRONCHOSPASM AGGRAVATED	2					2
	CORYZA					1	1
	COUGHING	3		1		13	17
	DYSPNOEA	6		1		30	37
	HOARSENESS	1					1
	INTERSTITIAL LUNG DISEASE	1			1	1	3
	NASAL CONGESTION	1					1

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Respiratory	NASAL DRYNESS					1	1
	PHARYNGITIS	1				1	2
	PNEUMONIA	1				3	4
	PNEUMONIA INTERSTITIAL					1	1
	PULMONARY DISORDERS					1	1
	PULMONARY FIBROSIS	1				1	2
	PULMONARY OEDEMA					1	1
	RESPIRATORY DISORDER					1	1
	RESPIRATORY FAILURE					1	1
	RHINITIS	1				2	3
	SINUSITIS	1				1	2
	THROAT IRRITATION	1				1	2
	THROAT TIGHTNESS					6	6
	*** Total for Group ***	20		2	1	68	91
	Skin and Appendages	ALOPECIA	6				34
ALOPECIA AREATA						1	1
ANGIOEDEMA		4		2		8	14
BULLOUS ERUPTION		2				4	6
DERMATITIS		2				2	4
DERMATITIS EXFOLIATIVE						1	1
DERMATITIS LICHENOID		1					1
DERMOGRAPHIA		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

(Continued)

Statins

RGROUP	reaction	Medicine					Total	
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-		
		TATIN	ATIN	ATIN	TATIN	ATIN		
		N	N	N	N	N		
Skin and Appendages	HERPES SIMPLEX	1					1	
	LE SYNDROME	1				1	2	
	LUPUS ERYTHEMATOSUS SYSTEMIC	1					1	
	MACULAR RASH	1					1	
	MELANOMA MALIGNANT	2					2	
	NAIL DISORDER					1	1	
	PEMPHIGOID REACTION					1	1	
	PHOTOSENSITIVITY REACTION	1				7	8	
	PRURITUS	11				28	39	
	PRURITUS ANI	1					1	
	PSORIASIS AGGRAVATED					1	1	
	PURPURA					5	5	
	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 ***		80		3	2	191	276

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Special Senses	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
	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					9	9
	VISION DECREASED	1					1
	XEROPHTHALMIA					3	3
	*** Total for Group ***		14		1	1	60
Urinary	ANURIA					1	1
	DYSURIA			1		1	2
	ENURESIS					1	1
	HAEMATURIA					5	5

(Continued)

Statins

RGROUP	reaction	Medicine					Total
		ATORVAS-	FLUVAST-	PRAVAST-	ROSUVAS-	SIMVAST-	
		TATIN	ATIN	ATIN	TATIN	ATIN	
		N	N	N	N	N	
Urinary	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				27	28
	RENAL FAILURE AGGRAVATED					3	3
	RENAL FAILURE NOS					3	3
	RENAL FUNCTION ABNORMAL	1				4	5
	RENAL IMPAIRMENT	1					1
	RENAL PAIN					3	3
	RETROPERITONEAL FIBROSIS	1					1
	URINE ABNORMAL					3	3
	URINE DISCOLOURATION	4				1	5
	URINE FLOW DECREASED	1					1
	URINE ODOUR FOUL	1				1	2
	*** Total for Group ***	17		3		65	85
Total Reactions		1005	3	30	50	2895	3983