Table 59 Completed.

Number and (Percent) of Patients

Body System/Organ Class and Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
RENAL & URINARY SYSTEM DISORDERS	**1 (0.4)**	**0**	**1 (0.1)**	**0**
CYSTOCELE	0	0	1 (0.1)	0
RENAL CALCULUS	1 (0.4)	0	0	0
RESPIRATORY SYSTEM DISORDERS	**2 (0.8)**	**1 (0.4)**	**2 (0.2)**	**2 (0.2)**
ASTHMA	0	0	1 (0.1)	0
BRONCHITIS AGGRAVATED	0	0	0	1 (0.1)
CHRONIC OBSTRUCTIVE AIRWAY DISEASE	1 (0.4)	0	0	0
DYSPNEA	0	1 (0.4)	1 (0.1)	0
PLEURAL EFFUSION	1 (0.4)	1 (0.4)	0	0
PNEUMOTHORAX	0	1 (0.4)	0	0
PULMONARY NODULE	0	0	0	1 (0.1)
RESPIRATORY INSUFFICIENCY	0	0	1 (0.1)	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	**0**	**0**	**1 (0.1)**	**0**
SKIN COLD CLAMMY	0	0	1 (0.1)	0
SURGICAL AND MEDICAL PROCEDURES	**1 (0.4)**	**0**	**2 (0.2)**	**1 (0.1)**
CHOLECYSTECTOMY	0	0	1 (0.1)	0
PROCEDURE (NO ADVERSE EVENT)	0	0	1 (0.1)	1 (0.1)
TUMOR EXCISION	1 (0.4)	0	0	0
VASCULAR (EXTRACARDIAC) DISORDERS	**0**	**0**	**2 (0.2)**	**1 (0.1)**
ARTERIAL OCCLUSION NOS	0	0	1 (0.1)	1 (0.1)
CAROTID ARTERY STENOSIS	0	0	1 (0.1)	0

a: SGOT = AST; SGPT = ALT. Protocols specified that elevated ALT or AST at least three times the upper limit of the reference range (≥3xULN) on two consecutive occasions at least 1 week apart should be considered a serious adverse event.

b: Protocols specified that elevated CPK ≥10xULN, or ≥5xULN with symptoms of myopathy in the absence of muscle trauma, on two consecutive occasions at least 48 hours apart should be considered a serious adverse event.

EZ=ezetimibe 10 mg; All Statins=all doses of all statins; SAE=serious adverse event.

Table 60 Primary Hypercholesterolemia
Factorial Coadministration Pool
Serious Adverse Events (SAEs)
Considered As Treatment-Related By Investigators

Body System/Organ Class and Adverse Event	Number And (Percent) Of Patients			
	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
SUBJECTS REPORTING ANY SAE	**0**	**1 (0.4)**	**1 (0.1)**	**10 (1.1)**
BODY AS A WHOLE - GENERAL DISORDERS	**0**	**0**	**0**	**1 (0.1)**
WEAKNESS	0	0	0	1 (0.1)
CARDIOVASCULAR DISORDERS, GENERAL	**0**	**0**	**0**	**1 (0.1)**
MYOCARDIAL INFARCTION	0	0	0	1 (0.1)
LIVER AND BILIARY SYSTEM DISORDERS[a]	**0**	**1 (0.4)**	**1 (0.1)**	**8 (0.9)**
HEPATIC ENZYMES INCREASED	0	0	0	4 (0.4)
SGOT INCREASED	0	1 (0.4)	1 (0.1)	0
SGPT INCREASED	0	1 (0.4)	1 (0.1)	4 (0.4)
METABOLIC AND NUTRITIONAL DISORDERS	**0**	**0**	**0**	**1 (0.1)**
CREATINE PHOSPHOKINASE INCREASED[b]	0	0	0	1 (0.1)
MUSCULO-SKELETAL SYSTEM DISORDERS	**0**	**0**	**0**	**1 (0.1)**
MYALGIA	0	0	0	1 (0.1)

a: SGOT = AST; SGPT = ALT. Protocols specified that elevated ALT or AST at least three times the upper limit of the reference range (≥3xULN) on two consecutive occasions at least 1 week apart should be considered a serious adverse event.

b: Protocols specified that elevated CPK ≥10xULN, or ≥5xULN with symptoms of myopathy in the absence of muscle trauma, on two consecutive occasions at least 48 hours apart should be considered a serious adverse event.

EZ=ezetimibe 10 mg; All Statins=all doses of all statins; SAE=serious adverse event.

Note: "Treatment-related" means judged to be at least possibly related to treatment by the investigator.

Table 61 Primary Hypercholesterolemia
Factorial Coadministration Pool
Discontinuations Due To Adverse Events (AEs)

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
SUBJECTS REPORTING ANY ADVERSE EVENT	**16 (6.2)**	**13 (5.0)**	**40 (4.3)**	**53 (5.7)**
AUTONOMIC NERVOUS SYSTEM DISORDERS	**0**	**0**	**0**	**1 (0.1)**
HOT FLUSHES	0	0	0	1 (0.1)
BENIGN & MALIGNANT NEOPLASMS (INCLUDING CYSTS AND POLYPS)	**0**	**3 (1.1)**	**1 (0.1)**	**1 (0.1)**
BREAST NEOPLASM MALIGNANT FEMALE	0	1 (0.6)	1 (0.2)	0
GASTRIC CARCINOMA	0	1 (0.4)	0	0
MENINGIOMA	0	1 (0.4)	0	0
PULMONARY CARCINOMA	0	0	0	1 (0.1)
BODY AS A WHOLE - GENERAL DISORDERS	**4 (1.5)**	**2 (0.8)**	**5 (0.5)**	**11 (1.2)**
ABDOMINAL MASS	0	0	0	1 (0.1)
ASTHENIA	0	0	1 (0.1)	0
CHEST PAIN	0	0	0	2 (0.2)
DIZZINESS	1 (0.4)	0	1 (0.1)	0
EDEMA GENERALIZED	1 (0.4)	0	0	0
EDEMA LEGS	1 (0.4)	0	1 (0.1)	1 (0.1)
EDEMA PERIPHERAL	1 (0.4)	0	0	1 (0.1)
FATIGUE	1 (0.4)	0	2 (0.2)	4 (0.4)
HEADACHE	0	2 (0.8)	1 (0.1)	3 (0.3)
WEAKNESS	0	0	0	2 (0.2)
CARDIOVASCULAR DISORDERS, GENERAL	**1 (0.4)**	**1 (0.4)**	**3 (0.3)**	**1 (0.1)**
ANGINA PECTORIS	0	0	0	1 (0.1)
HYPERTENSION	1 (0.4)	1 (0.4)	1 (0.1)	0
MYOCARDIAL INFARCTION	0	0	2 (0.2)	0
CENTR AND PERIPH NERV SYST DISORDERS	**1 (0.4)**	**0**	**4 (0.4)**	**1 (0.1)**
CEREBROVASCULAR ACCIDENT NOS	1 (0.4)	0	0	0
CEREBROVASCULAR DISORDER	0	0	0	1 (0.1)
HYPERTONIA	0	0	1 (0.1)	0
HYPOESTHESIA	0	0	1 (0.1)	0
MIGRAINE	0	0	2 (0.2)	0
DISORDERS OF BLOOD AND LYMPHATIC SYSTEM	**0**	**0**	**0**	**1 (0.1)**
HEMATOCRIT DECREASED	0	0	0	1 (0.1)
HEMOGLOBIN DECREASED	0	0	0	1 (0.1)
DISORDERS OF THE EAR & LABYRINTH	**0**	**0**	**0**	**1 (0.1)**

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Table 61 Continued.

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
TINNITUS	0	0	0	1 (0.1)
DISORDERS OF THE EYE	**0**	**0**	**2 (0.2)**	**0**
CONJUNCTIVAL HEMORRHAGE	0	0	1 (0.1)	0
PHOTOPHOBIA	0	0	1 (0.1)	0
VISION BLURRED	0	0	1 (0.1)	0
DISORDERS OF THE IMMUNE SYSTEM	**1 (0.4)**	**0**	**1 (0.1)**	**0**
ALLERGY AGGRAVATED	0	0	1 (0.1)	0
INFLAMMATION, NON- SPECIFIC	1 (0.4)	0	0	0
DISORDERS OF THE REPRODUCTIVE SYSTEM AND BREAST	**0**	**2 (0.8)**	**1 (0.1)**	**0**
BREAST PAIN	0	1 (0.6)	0	0
OVARIAN MASS	0	1 (0.6)	0	0
PREGNANCY UNINTENDED	0	0	1 (0.2)	0
ENDOCRINE DISORDERS	**0**	**0**	**1 (0.1)**	**1 (0.1)**
DIABETES MELLITUS	0	0	1 (0.1)	0
TSH INCREASED	0	0	0	1 (0.1)
GASTRO-INTESTINAL SYSTEM DISORDERS	**4 (1.5)**	**1 (0.4)**	**8 (0.9)**	**13 (1.4)**
ABDOMINAL DISTENSION	1 (0.4)	0	1 (0.1)	1 (0.1)
ABDOMINAL PAIN	0	0	0	3 (0.3)
COLITIS	0	0	0	1 (0.1)
CONSTIPATION	1 (0.4)	0	0	0
DIARRHEA	2 (0.8)	0	1 (0.1)	2 (0.2)
DIVERTICULITIS	0	0	1 (0.1)	0
DIVERTICULOSIS	0	1 (0.4)	0	0
DYSPEPSIA	0	0	1 (0.1)	2 (0.2)
ESOPHAGOSPASM	0	0	0	1 (0.1)
FLATULENCE	0	0	0	1 (0.1)
FREQUENT BOWEL MOVEMENTS	0	0	0	1 (0.1)
GASTRITIS	0	0	0	1 (0.1)
GASTROENTERITIS	0	0	0	1 (0.1)
ILEITIS	0	1 (0.4)	0	0
ILEUS	0	0	1 (0.1)	0
NAUSEA	1 (0.4)	0	5 (0.5)	3 (0.3)
RECTAL BLEEDING	0	0	1 (0.1)	0
HEART RATE AND RHYTHM DISORDERS	**0**	**0**	**1 (0.1)**	**0**
PALPITATION	0	0	1 (0.1)	0
INFECTION AND INFESTATIONS	**1 (0.4)**	**0**	**1 (0.1)**	**1 (0.1)**
PNEUMONIA	0	0	1 (0.1)	0
UPPER RESP TRACT INFECTION	1 (0.4)	0	0	1 (0.1)

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Table 61 Continued.

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
LIVER AND BILIARY SYSTEM DISORDERS[a]	**1 (0.4)**	**2 (0.8)**	**3 (0.3)**	**10 (1.1)**
GAMMA-GT INCREASED	0	2 (0.8)	0	1 (0.1)
HEPATIC ENZYMES INCREASED	0	1 (0.4)	1 (0.1)	6 (0.6)
SGOT INCREASED	1 (0.4)	0	2 (0.2)	2 (0.2)
SGPT INCREASED	1 (0.4)	1 (0.4)	2 (0.2)	4 (0.4)
METABOLIC AND NUTRITIONAL DISORDERS	**2 (0.8)**	**2 (0.8)**	**1 (0.1)**	**4 (0.4)**
CREATINE PHOSPHOKINASE INCREASED[b]	2 (0.8)	0	1 (0.1)	4 (0.4)
PHOSPHATASE ALKALINE INCREASED	0	2 (0.8)	0	0
MUSCULO-SKELETAL SYSTEM DISORDERS	**5 (1.9)**	**3 (1.1)**	**6 (0.6)**	**14 (1.5)**
ARTHRALGIA	2 (0.8)	1 (0.4)	4 (0.4)	0
ARTHROPATHY	1 (0.4)	0	0	0
BACK PAIN	0	0	0	2 (0.2)
CRAMPS LEGS	1 (0.4)	0	0	1 (0.1)
MUSCLE CRAMPS	0	0	1 (0.1)	0
MUSCLE SPRAIN	0	1 (0.4)	0	0
MUSCLE WEAKNESS	1 (0.4)	1 (0.4)	0	2 (0.2)
MUSCULO-SKELETAL PAIN	1 (0.4)	0	1 (0.1)	3 (0.3)
MYALGIA	1 (0.4)	0	5 (0.5)	8 (0.9)
MYALGIA AGGRAVATED	0	0	0	1 (0.1)
PLATELET, BLEEDING AND CLOTTING DISORD	**0**	**0**	**1 (0.1)**	**1 (0.1)**
COAGULATION DISORDER	0	0	0	1 (0.1)
THROMBOCYTOPENIA	0	0	1 (0.1)	0
PSYCHIATRIC DISORDERS	**0**	**1 (0.4)**	**2 (0.2)**	**1 (0.1)**
INSOMNIA	0	1 (0.4)	2 (0.2)	1 (0.1)
RENAL & URINARY SYSTEM DISORDERS	**0**	**0**	**1 (0.1)**	**0**
HEMATURIA	0	0	1 (0.1)	0
RESPIRATORY SYSTEM DISORDERS	**1 (0.4)**	**1 (0.4)**	**3 (0.3)**	**3 (0.3)**
ASTHMA AGGRAVATED	0	0	1 (0.1)	0
BRONCHITIS	0	0	1 (0.1)	0
BRONCHITIS AGGRAVATED	0	0	0	1 (0.1)
CHEST X-RAY ABNORMAL	0	0	0	1 (0.1)
DYSPNEA	1 (0.4)	1 (0.4)	1 (0.1)	1 (0.1)

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Table 61 Completed.

Body System/Organ Class and Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
	Number And (Percent) Of Patients			
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	**0**	**2 (0.8)**	**5 (0.5)**	**2 (0.2)**
ALOPECIA	0	0	1 (0.1)	0
ECZEMA	0	0	0	1 (0.1)
HAIR TEXTURE ABNORMAL	0	0	1 (0.1)	0
PRURITUS	0	0	1 (0.1)	1 (0.1)
RASH	0	1 (0.4)	1 (0.1)	1 (0.1)
URTICARIA	0	1 (0.4)	1 (0.1)	0
VASCULAR (EXTRACARDIAC) DISORDERS	**0**	**0**	**0**	**1 (0.1)**
CAROTID ARTERY STENOSIS	0	0	0	1 (0.1)

a: SGOT = AST; SGPT = ALT. Several protocols specified that elevated ALT or AST at least three times the upper limit of the reference range (≥3xULN) on two consecutive occasions at least 1 week apart should result in discontinuation.

b: Several protocols specified that elevated CPK ≥10xULN, or ≥5xULN with symptoms of myopathy in the absence of muscle trauma, on two consecutive occasions at least 48 hours apart should result in discontinuation.

EZ=ezetimibe 10 mg; All Statins=all doses of all statins; NOS=not otherwise specified.

Table 62 Primary Hypercholesterolemia
Factorial Coadministration Pool
Discontinuations Due To Adverse Events (AEs)
Considered As Treatment-related By Investigators

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
SUBJECTS REPORTING ANY ADVERSE EVENT	**10 (3.9)**	**7 (2.7)**	**23 (2.5)**	**34 (3.7)**
BODY AS A WHOLE - GENERAL DISORDERS	**3 (1.2)**	**1 (0.4)**	**4 (0.4)**	**5 (0.5)**
ASTHENIA	0	0	1 (0.1)	0
CHEST PAIN	0	0	0	1 (0.1)
DIZZINESS	0	0	1 (0.1)	0
EDEMA GENERALIZED	1 (0.4)	0	0	0
EDEMA LEGS	1 (0.4)	0	1 (0.1)	1 (0.1)
EDEMA PERIPHERAL	1 (0.4)	0	0	1 (0.1)
FATIGUE	1 (0.4)	0	1 (0.1)	1 (0.1)
HEADACHE	0	1 (0.4)	1 (0.1)	1 (0.1)
WEAKNESS	0	0	0	2 (0.2)
CARDIOVASCULAR DISORDERS, GENERAL	**1 (0.4)**	**1 (0.4)**	**1 (0.1)**	**0**
HYPERTENSION	1 (0.4)	1 (0.4)	1 (0.1)	0
CENTR AND PERIPH NERV SYST DISORDERS	**0**	**0**	**3 (0.3)**	**0**
HYPOESTHESIA	0	0	1 (0.1)	0
MIGRAINE	0	0	2 (0.2)	0
DISORDERS OF BLOOD AND LYMPHATIC SYSTEM	**0**	**0**	**0**	**1 (0.1)**
HEMATOCRIT DECREASED	0	0	0	1 (0.1)
HEMOGLOBIN DECREASED	0	0	0	1 (0.1)
DISORDERS OF THE EYE	**0**	**0**	**1 (0.1)**	**0**
PHOTOPHOBIA	0	0	1 (0.1)	0
VISION BLURRED	0	0	1 (0.1)	0
DISORDERS OF THE IMMUNE SYSTEM	**1 (0.4)**	**0**	**0**	**0**
INFLAMMATION, NON- SPECIFIC	1 (0.4)	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS	**3 (1.2)**	**0**	**4 (0.4)**	**9 (1.0)**
ABDOMINAL DISTENSION	1 (0.4)	0	0	0
ABDOMINAL PAIN	0	0	0	2 (0.2)
CONSTIPATION	1 (0.4)	0	0	0
DIARRHEA	1 (0.4)	0	1 (0.1)	1 (0.1)
DYSPEPSIA	0	0	0	2 (0.2)
ESOPHAGOSPASM	0	0	0	1 (0.1)
FLATULENCE	0	0	0	1 (0.1)
FREQUENT BOWEL MOVEMENTS	0	0	0	1 (0.1)
GASTRITIS	0	0	0	1 (0.1)
GASTROENTERITIS	0	0	0	1 (0.1)
NAUSEA	0	0	3 (0.3)	2 (0.2)
HEART RATE AND RHYTHM DISORDERS	**0**	**0**	**1 (0.1)**	**0**
PALPITATION	0	0	1 (0.1)	0
LIVER AND BILIARY SYSTEM DISORDERS[a]	**0**	**1 (0.4)**	**3 (0.3)**	**10 (1.1)**
GAMMA-GT INCREASED	0	0	0	1 (0.1)
HEPATIC ENZYMES INCREASED	0	1 (0.4)	1 (0.1)	6 (0.6)
SGOT INCREASED	0	0	2 (0.2)	2 (0.2)
SGPT INCREASED	0	0	2 (0.2)	4 (0.4)
METABOLIC AND NUTRITIONAL DISORDERS	**1 (0.4)**	**0**	**1 (0.1)**	**3 (0.3)**
CREATINE PHOSPHOKINASE INCREASED[b]	1 (0.4)	0	1 (0.1)	3 (0.3)

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Table 62 Completed.

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
MUSCULO-SKELETAL SYSTEM DISORDERS	**4 (1.5)**	**1 (0.4)**	**3 (0.3)**	**10 (1.1)**
ARTHRALGIA	2 (0.8)	1 (0.4)	2 (0.2)	0
ARTHROPATHY	1 (0.4)	0	0	0
BACK PAIN	0	0	0	1 (0.1)
CRAMPS LEGS	1 (0.4)	0	0	1 (0.1)
MUSCLE CRAMPS	0	0	1 (0.1)	0
MUSCLE WEAKNESS	1 (0.4)	0	0	1 (0.1)
MUSCULO-SKELETAL PAIN	1 (0.4)	0	1 (0.1)	2 (0.2)
MYALGIA	0	0	3 (0.3)	7 (0.8)
PLATELET, BLEEDING AND CLOTTING DISORD	**0**	**0**	**0**	**1 (0.1)**
COAGULATION DISORDER	0	0	0	1 (0.1)
PSYCHIATRIC DISORDERS	**0**	**1 (0.4)**	**2 (0.2)**	**0**
INSOMNIA	0	1 (0.4)	2 (0.2)	0
RESPIRATORY SYSTEM DISORDERS	**1 (0.4)**	**1 (0.4)**	**3 (0.3)**	**1 (0.1)**
ASTHMA AGGRAVATED	0	0	1 (0.1)	0
BRONCHITIS	0	0	1 (0.1)	0
DYSPNEA	1 (0.4)	1 (0.4)	1 (0.1)	1 (0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	**0**	**2 (0.8)**	**3 (0.3)**	**2 (0.2)**
ECZEMA	0	0	0	1 (0.1)
PRURITUS	0	0	1 (0.1)	1 (0.1)
RASH	0	1 (0.4)	1 (0.1)	1 (0.1)
URTICARIA	0	1 (0.4)	1 (0.1)	0

a: SGOT = AST; SGPT = ALT. Protocols specified that elevated ALT or AST at least three times the upper limit of the reference range (≥3xULN) on two consecutive occasions at least 1 week apart should result in discontinuation.

b: Protocols specified that elevated CPK ≥10xULN, or ≥5xULN with symptoms of myopathy in the absence of muscle trauma, on two consecutive occasions at least 48 hours apart should result in discontinuation.

EZ=ezetimibe 10 mg; All Statins=all doses of all statins.

Note: "Treatment-related" means judged to be at least possibly related to treatment by the investigator.

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Table 63 Primary Hypercholesterolemia
Factorial Coadministration Pool
Adverse Events (AEs) Of Any Severity
Reported For ≥2% Of Patients In Any Pooled Treatment Group

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
SUBJECTS REPORTING ANY ADVERSE EVENT	**166 (64.1)**	**177 (67.6)**	**606 (64.7)**	**593 (64.1)**
BODY AS A WHOLE - GENERAL DISORDERS				
CHEST PAIN	3 (1.2)	9 (3.4)	19 (2.0)	17 (1.8)
DIZZINESS	3 (1.2)	7 (2.7)	13 (1.4)	17 (1.8)
EDEMA LEGS	7 (2.7)	1 (0.4)	6 (0.6)	14 (1.5)
FATIGUE	5 (1.9)	5 (1.9)	13 (1.4)	26 (2.8)
HEADACHE	14 (5.4)	21 (8.0)	68 (7.3)	58 (6.3)
GASTRO-INTESTINAL SYSTEM DISORDERS				
ABDOMINAL PAIN	6 (2.3)	7 (2.7)	29 (3.1)	32 (3.5)
CONSTIPATION	6 (2.3)	8 (3.1)	18 (1.9)	10 (1.1)
DIARRHEA	4 (1.5)	9 (3.4)	27 (2.9)	26 (2.8)
DYSPEPSIA	6 (2.3)	8 (3.1)	24 (2.6)	16 (1.7)
NAUSEA	12 (4.6)	8 (3.1)	47 (5.0)	33 (3.6)
INFECTION AND INFESTATIONS				
PHARYNGITIS	5 (1.9)	8 (3.1)	23 (2.5)	21 (2.3)
SINUSITIS	5 (1.9)	12 (4.6)	34 (3.6)	32 (3.5)
UPPER RESP TRACT INFECTION	28 (10.8)	34 (13.0)	127 (13.6)	109 (11.8)
LIVER AND BILIARY SYSTEM DISORDERS[a]				
SGOT INCREASED	1 (0.4)	1 (0.4)	3 (0.3)	26 (2.8)
SGPT INCREASED	2 (0.8)	3 (1.1)	7 (0.7)	30 (3.2)
MUSCULO-SKELETAL SYSTEM DISORDERS				
ARTHRALGIA	6 (2.3)	10 (3.8)	40 (4.3)	31 (3.4)
BACK PAIN	9 (3.5)	9 (3.4)	35 (3.7)	40 (4.3)
MUSCULO-SKELETAL PAIN	13 (5.0)	13 (5.0)	39 (4.2)	33 (3.6)
MYALGIA	12 (4.6)	13 (5.0)	38 (4.1)	42 (4.5)
PSYCHIATRIC DISORDERS				
INSOMNIA	6 (2.3)	3 (1.1)	16 (1.7)	16 (1.7)
RESPIRATORY SYSTEM DISORDERS				
COUGHING	9 (3.5)	8 (3.1)	21 (2.2)	23 (2.5)
NASAL CONGESTION	5 (1.9)	6 (2.3)	13 (1.4)	17 (1.8)

a: SGOT = AST; SGPT = ALT.

EZ=ezetimibe 10 mg; All Statins=all doses of all statins.

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Table 64 Primary Hypercholesterolemia
Factorial Coadministration Pool
Adverse Events (AEs) Of Any Severity,
Considered As Treatment-Related By Investigators
Reported For ≥2% Of Patients In Any Pooled Treatment Group

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
SUBJECTS REPORTING ANY ADVERSE EVENT	**47 (18.1)**	**41 (15.6)**	**158 (16.9)**	**180 (19.5)**
LIVER AND BILIARY SYSTEM DISORDERS[a]				
SGOT INCREASED	0	1 (0.4)	3 (0.3)	21 (2.3)
SGPT INCREASED	1 (0.4)	2 (0.8)	7 (0.7)	25 (2.7)
MUSCULO-SKELETAL SYSTEM DISORDERS				
MYALGIA	4 (1.5)	3 (1.1)	20 (2.1)	23 (2.5)

a: SGOT = AST; SGPT = ALT.

EZ=ezetimibe 10 mg; All Statins=all doses of all statins.

Note: "Treatment-related" means judged to be at least possibly related to treatment by the investigator.

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Table 65 Primary Hypercholesterolemia
Factorial Coadministration Pool
Severe or Life-Threatening Adverse Events (AEs)

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
SUBJECTS REPORTING ANY ADVERSE EVENT	**13 (5.0)**	**14 (5.3)**	**52 (5.6)**	**56 (6.1)**
AUTONOMIC NERVOUS SYSTEM DISORDERS	**0**	**0**	**0**	**1 (0.1)**
HOT FLUSHES	0	0	0	1 (0.1)
BENIGN & MALIGNANT NEOPLASMS (INCLUDING CYSTS AND POLYPS)	**0**	**4 (1.5)**	**1 (0.1)**	**2 (0.2)**
BREAST NEOPLASM MALIGNANT FEMALE	0	1 (0.6)	1 (0.2)	0
GASTRIC CARCINOMA	0	1 (0.4)	0	0
MENINGIOMA	0	1 (0.4)	0	0
NEOPLASM, BRAIN	0	1 (0.4)	0	0
PROSTATIC CANCER	0	0	0	1 (0.1)
PULMONARY CARCINOMA	0	1 (0.4)	0	0
RECTAL CARCINOMA	0	0	0	1 (0.1)
BODY AS A WHOLE - GENERAL DISORDERS	**2 (0.8)**	**4 (1.5)**	**9 (1.0)**	**8 (0.9)**
ABDOMINAL MASS	0	0	0	1 (0.1)
CHEST PAIN	0	1 (0.4)	2 (0.2)	2 (0.2)
DIZZINESS	1 (0.4)	0	0	2 (0.2)
EDEMA PERIPHERAL	1 (0.4)	0	0	0
FALL	0	1 (0.4)	0	0
FATIGUE	0	0	0	1 (0.1)
FATIGUE AGGRAVATED	0	0	0	1 (0.1)
FEVER	0	0	1 (0.1)	0
HEADACHE	0	2 (0.8)	3 (0.3)	1 (0.1)
POST-PROCEDURE PAIN	0	0	2 (0.2)	0
SYNCOPE	0	1 (0.4)	1 (0.1)	0
CARDIOVASCULAR DISORDERS, GENERAL	**2 (0.8)**	**0**	**2 (0.2)**	**1 (0.1)**
ANGINA PECTORIS	0	0	0	1 (0.1)
CARDIAC FAILURE	1 (0.4)	0	0	0
CORONARY ARTERY DISORDER	1 (0.4)	0	0	0
MITRAL INSUFFICIENCY	1 (0.4)	0	0	0
MYOCARDIAL INFARCTION	0	0	2 (0.2)	1 (0.1)
TRICUSPID VALVE INCOMPETENCE	1 (0.4)	0	0	0

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Table 65 Continued.

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
CENTR AND PERIPH NERV SYST DISORDERS	**0**	**2 (0.8)**	**4 (0.4)**	**4 (0.4)**
CEREBROVASCULAR DISORDER	0	0	0	1 (0.1)
HYPERTONIA	0	0	1 (0.1)	1 (0.1)
LOSS OF CONSCIOUSNESS	0	1 (0.4)	0	0
MIGRAINE	0	0	2 (0.2)	1 (0.1)
RESTLESS LEG SYNDROME	0	0	0	1 (0.1)
SOMNOLENCE	0	1 (0.4)	0	0
TRANSIENT ISCHEMIC ATTACK	0	0	1 (0.1)	0
DISORDERS OF THE EAR & LABYRINTH	**1 (0.4)**	**0**	**1 (0.1)**	**0**
HEARING IMPAIRMENT	1 (0.4)	0	0	0
LABYRINTHINE DISORDER	0	0	1 (0.1)	0
DISORDERS OF THE EYE	**0**	**0**	**0**	**1 (0.1)**
LACRIMAL DUCT OBSTRUCTION	0	0	0	1 (0.1)
DISORDERS OF THE IMMUNE SYSTEM	**0**	**0**	**1 (0.1)**	**0**
ALLERGY	0	0	1 (0.1)	0
DISORDERS OF THE REPRODUCTIVE SYSTEM AND BREAST	**0**	**1 (0.4)**	**1 (0.1)**	**1 (0.1)**
BREAST MASS	0	0	1 (0.2)	0
OVARIAN MASS	0	1 (0.6)	0	0
UTERINE HEMORRHAGE	0	0	0	1 (0.2)
GASTRO-INTESTINAL SYSTEM DISORDERS	**2 (0.8)**	**6 (2.3)**	**10 (1.1)**	**13 (1.4)**
ABDOMINAL DISTENSION	0	1 (0.4)	0	0
ABDOMINAL PAIN	0	2 (0.8)	3 (0.3)	2 (0.2)
ANAL STENOSIS	0	0	0	1 (0.1)
CONSTIPATION	1 (0.4)	0	0	1 (0.1)
DIARRHEA	1 (0.4)	0	3 (0.3)	0
DIVERTICULITIS	0	0	1 (0.1)	1 (0.1)
DIVERTICULOSIS	0	1 (0.4)	0	0
DYSPHAGIA	0	0	1 (0.1)	0
GASTRITIS	0	0	0	2 (0.2)
GASTROENTERITIS	0	1 (0.4)	1 (0.1)	0
GASTROESOPHAGEAL REFLUX	0	0	1 (0.1)	0
ILEITIS	0	1 (0.4)	0	0
IRRITABLE BOWEL SYNDROME	0	0	1 (0.1)	0
MELENA	0	0	0	1 (0.1)
NAUSEA	0	1 (0.4)	0	3 (0.3)
RETCHING	0	0	0	1 (0.1)
RUQ PAIN	0	1 (0.4)	0	1 (0.1)
TOOTHACHE	0	0	0	1 (0.1)
VOMITING	0	1 (0.4)	1 (0.1)	4 (0.4)

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Table 65 Continued.

Body System/Organ Class and Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
	Number And (Percent) Of Patients			
HEART RATE AND RHYTHM DISORDERS	**0**	**0**	**0**	**2 (0.2)**
ECG ABNORMAL	0	0	0	1 (0.1)
FIBRILLATION ATRIAL	0	0	0	1 (0.1)
TACHYCARDIA VENTRICULAR	0	0	0	1 (0.1)
INFECTION AND INFESTATIONS	**0**	**0**	**6 (0.6)**	**5 (0.5)**
HERPES ZOSTER	0	0	1 (0.1)	0
PNEUMONIA	0	0	1 (0.1)	1 (0.1)
SINUSITIS	0	0	1 (0.1)	2 (0.2)
STAPHYLOCOCCAL INFECTION NOS	0	0	0	1 (0.1)
UPPER RESP TRACT INFECTION	0	0	3 (0.3)	1 (0.1)
INJURY AND POISONING	**0**	**0**	**1 (0.1)**	**1 (0.1)**
INJURY ACCIDENTAL	0	0	1 (0.1)	0
TRAUMA	0	0	0	1 (0.1)
LIVER AND BILIARY SYSTEM DISORDERS[a]	**1 (0.4)**	**0**	**2 (0.2)**	**5 (0.5)**
HEPATIC ENZYMES INCREASED	0	0	1 (0.1)	2 (0.2)
SGOT INCREASED	1 (0.4)	0	1 (0.1)	2 (0.2)
SGPT INCREASED	1 (0.4)	0	1 (0.1)	3 (0.3)
METABOLIC AND NUTRITIONAL DISORDERS	**1 (0.4)**	**0**	**3 (0.3)**	**3 (0.3)**
CREATINE PHOSPHOKINASE INCREASED	1 (0.4)	0	1 (0.1)	2 (0.2)
DEHYDRATION	0	0	0	1 (0.1)
GOUT	0	0	2 (0.2)	0
MUSCULO-SKELETAL SYSTEM DISORDERS	**3 (1.2)**	**3 (1.1)**	**15 (1.6)**	**12 (1.3)**
ARTHRALGIA	1 (0.4)	0	3 (0.3)	1 (0.1)
ARTHRALGIA AGGRAVATED	0	1 (0.4)	0	0
ARTHROPATHY	0	0	1 (0.1)	0
BACK PAIN	0	0	2 (0.2)	3 (0.3)
BACK PAIN, AGGRAVATED	0	0	0	2 (0.2)
FASCIITIS	0	0	1 (0.1)	0
HERNIA	0	0	1 (0.1)	0
MUSCLE SPRAIN	0	1 (0.4)	2 (0.2)	1 (0.1)
MUSCULO-SKELETAL PAIN	2 (0.8)	2 (0.8)	2 (0.2)	3 (0.3)
MYALGIA	0	0	2 (0.2)	2 (0.2)
MYALGIA AGGRAVATED	0	0	0	1 (0.1)
SPINAL DISORDER	0	0	1 (0.1)	0
TENDINITIS	0	0	1 (0.1)	0
PLATELET, BLEEDING AND CLOTTING DISORD	**0**	**0**	**0**	**1 (0.1)**
BRUISING	0	0	0	1 (0.1)

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Table 65 Completed.

Body System/Organ Class and Adverse Event	Number And (Percent) Of Patients: Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
PSYCHIATRIC DISORDERS	**1 (0.4)**	**0**	**0**	**0**
AMNESIA	1 (0.4)	0	0	0
RENAL & URINARY SYSTEM DISORDERS	**1 (0.4)**	**1 (0.4)**	**0**	**0**
DYSURIA	0	1 (0.4)	0	0
RENAL CALCULUS	1 (0.4)	0	0	0
RESPIRATORY SYSTEM DISORDERS	**3 (1.2)**	**1 (0.4)**	**4 (0.4)**	**4 (0.4)**
BRONCHITIS	0	0	0	1 (0.1)
BRONCHITIS AGGRAVATED	0	0	0	1 (0.1)
CHRONIC OBSTRUCTIVE AIRWAY DISEASE	1 (0.4)	0	0	0
COUGHING	0	0	1 (0.1)	0
COUGHING AGGRAVATED	1 (0.4)	0	0	0
DYSPNEA	0	1 (0.4)	0	2 (0.2)
NASAL CONGESTION	0	0	1 (0.1)	0
PLEURAL EFFUSION	1 (0.4)	1 (0.4)	0	0
PNEUMOTHORAX	0	1 (0.4)	0	0
RESPIRATORY INSUFFICIENCY	0	0	1 (0.1)	0
SINUS CONGESTION	0	0	1 (0.1)	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	**0**	**0**	**0**	**1 (0.1)**
ECZEMA	0	0	0	1 (0.1)
SURGICAL AND MEDICAL PROCEDURES	**0**	**0**	**2 (0.2)**	**1 (0.1)**
CHOLECYSTECTOMY	0	0	1 (0.1)	0
PROCEDURE (NO ADVERSE EVENT)	0	0	1 (0.1)	1 (0.1)
VASCULAR (EXTRACARDIAC) DISORDERS	**0**	**0**	**1 (0.1)**	**1 (0.1)**
ARTERIAL OCCLUSION NOS	0	0	1 (0.1)	1 (0.1)

a: SGOT = AST; SGPT = ALT.

EZ=ezetimibe 10 mg; All Statins=all doses of all statins; NOS=not otherwise specified.

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Table 66 Primary Hypercholesterolemia
Factorial Coadministration Pool
Blood Urea Nitrogen (BUN) And Creatinine
Postbaseline Values Outside Prespecified Limits

Prespecified Limits	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=935)	EZ + All Statins (n=925)
		Number And (Percent) Of Patients		
Blood Urea Nitrogen (BUN); Reference Range: 5–20 mg/dL				
<5 mg/dL	0/254	0/259	1/923 (0.1)	0/912
>20 mg/dL	47/254 (18.5)	58/259 (22.4)	153/923 (16.6)	176/912 (19.3)
Creatinine; Reference Range: 0.7–1.4 mg/dL				
>1.4 mg/dL	5/255 (2.0)	11/259 (4.2)	30/929 (3.2)	25/917 (2.7)

EZ = ezetimibe 10 mg; All Statins = all doses of all statins.

Note: These data are presented in the form X/Y, where X represents the number of subjects who met the criterion for a value outside prespecified limits as indicated, and Y represents the number of subjects who had at least one postbaseline observation for the test in question.

Table 66 A Primary Hypercholesterolemia
Factorial Coadministration Pool
Blood Urea Nitrogen (BUN) And Creatinine
Postbaseline Values Outside Prespecified Limits

Number And (Percent) Of Patients

Prespecified Limits	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
Blood Urea Nitrogen (BUN); Reference Range: 5–20 mg/dL				
US: <5 mg/dL SI: <1.785 mmol/L	0/254	0/259	1/923 (0.1)	0/912
US: >30 mg/dL SI: >10.7 mmol/L	4/254 (1.6)	1/259 (0.4)	7/923 (0.8)	10/912 (1.1)
Creatinine; Reference Range: 0.7–1.4 mg/dL				
US: >2 mg/dL SI: 176.8 µmol/L	0/255	0/259	0/929	1/917 (0.1)

EZ=ezetimibe 10 mg; All Statins=all doses of all statins.

Note: These data are presented in the form X/Y, where X represents the number of subjects who met the criterion for a value outside preespecified limits as indicated, and Y represents the number of subjects who had at least one postbaseline observation for the test in question.

APPEARS THIS WAY
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Table 67 Primary Hypercholesterolemia
Factorial Coadministration Pool
Blood Urea Nitrogen (BUN) And Creatinine
Mean And Median Changes From Baseline To Endpoint

Values	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
Blood Urea Nitrogen (BUN); Reference Range: 5–20 mg/dL				
Baseline Value (mg/dL)				
Mean	15.3	15.3	14.9	15.3
(SD, n)	(4.07, 259)	(4.27, 262)	(4.29, 936)	(4.12, 925)
Median	15	15	14	15
Change from Baseline to Endpoint (mg/dL)				
Mean	-0.213	-0.175	-0.193	0.146
(SD, n)	(3.38, 249)	(3.28, 252)	(3.38, 906)	(3.41, 888)
Median	0	0	0	0
Creatinine; Reference Range: 0.7–1.4 mg/dL				
Baseline Value (mg/dL)				
Mean	1.06	1.06	1.05	1.06
(SD, n)	(0.166, 259)	(0.174, 262)	(0.162, 936)	(0.164, 925)
Median	1	1	1	1.1
Change from Baseline to Endpoint (mg/dL)				
Mean	0.005	-0.013	-0.008	-0.008
(SD, n)	(0.084, 253)	(0.093, 254)	(0.091, 920)	(0.098, 908)
Median	0	0	0	0

EZ=ezetimibe 10 mg; All Statins=all doses of all statins; (SD, n) = standard deviation, number of subjects included in calculation of change.

Table 68 Primary Hypercholesterolemia
Factorial Coadministration Pool
Hematology: Platelet Count, White Blood Cell (WBC) Count, Hemoglobin, Hematocrit, And Prothrombin Time
Postbaseline Values Outside Prespecified Limits

Number And (Percent) Of Patients

Prespecified Limits	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
Platelet Count; Reference Range: 150–450 x 10^9/L				
<150x10^9/L	5/254 (2.0)	11/258 (4.3)	30/923 (3.3)	29/913 (3.2)
>450x10^9/L	1/254 (0.4)	3/258 (1.2)	9/923 (1.0)	7/913 (0.8)
White Blood Cell (WBC) Count; Reference Range: 4.8–10.8 x 10^9/L				
<4.8x10^9/L	100/254 (39.4)	89/258 (34.5)	271/923 (29.4)	261/913 (28.6)
>10.8x10^9/L	5/254 (2.0)	13/258 (5.0)	30/923 (3.3)	27/913 (3.0)
Hemoglobin; Reference Range: Female 12–16 g/dL; Male 14–18 g/dL				
F:<12; M:<14 g/dL	35/254 (13.8)	35/258 (13.6)	146/923 (15.8)	154/913 (16.9)
F:>16; M:>18 g/dL	0/254	2/258 (0.8)	4/923 (0.4)	5/913 (0.5)
Hematocrit; Reference Range: Female 36%–46%; Male 42%–54%				
F:<36%; M:<42%	50/254 (19.7)	46/258 (17.8)	195/923 (21.1)	213/913 (23.3)
F:>46%; M:>54%	8/254 (3.1)	7/258 (2.7)	18/923 (2.0)	24/913 (2.6)
Prothrombin Time (PT); Reference Range: predominantly 10.5–13.5 seconds[a]				
>ULN[a]	7/220 (3.2)	8/219 (3.7)	24/792 (3.0)	27/751 (3.6)

a: Most centers used the — laboratory for prothrombin time, with a reference range of 10.5 to 13.5 seconds. Several centers outside the USA used a different laboratory for prothrombin time: those that provided values in "seconds" had reference ranges of 7.5 to 12 seconds up to 12 to 19 seconds; those that provided values in units other than seconds are not included in the pool.

EZ = ezetimibe 10 mg; All Statins = all doses of all statins; ULN = upper limit of reference range.

Note: These data are presented in the form X/Y, where X represents the number of subjects who met the criterion for a value outside prespecified limits as indicated, and Y represents the number of subjects who had at least one postbaseline observation for the test in question.

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Table 68 A Primary Hypercholesterolemia
Factorial Coadministration Pool
Hematology: Platelet Count, White Blood Cell (WBC) Count, Hemoglobin, Hematocrit, And Prothrombin Time
Postbaseline Values Outside Prespecified Limits

Number And (Percent) Of Patients

Prespecified Limits	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
Platelet Count; Reference Range: 150–450 x 10^9/L				
US/SI: <100x10^9/L	0/254	1/258 (0.4)	6/923 (0.7)	1/913 (0.1)
US/SI: >450x10^9/L	1/254 (0.4)	3/258 (1.2)	9/923 (1.0)	7/913 (0.8)
White Blood Cell (WBC) Count; Reference Range: 4.8–10.8 x 10^9/L				
US/SI: <3.0x10^9/L	1/254 (0.4)	2/258 (0.8)	6/923 (0.7)	3/913 (0.3)
US/SI: >10.8x10^9/L	5/254 (2.0)	13/258 (5.0)	30/923 (3.3)	27/913 (3.0)
Hemoglobin; Reference Range: Female 12–16 g/dL; Male 14–18 g/dL				
US: F:<11/M:<13 g/dL SI: F:<110/M:<130 g/L	8/254 (3.1)	5/258 (1.9)	30/923 (3.3)	31/913 (3.4)
US: F:>16/M:>18 g/dL SI: F:>160/M:>180 g/L	0/254	2/258 (0.8)	4/923 (0.4)	5/913 (0.5)
Hematocrit; Reference Range: Female 36%–46%; Male 42%–54%				
F:<33/M:<39 %	11/254 (4.3)	8/258 (3.1)	38/923 (4.1)	45/913 (4.9)
F:>46/M:>54 %	8/254 (3.1)	7/258 (2.7)	18/923 (2.0)	24/913 (2.6)
Prothrombin Time (PT); Reference Range: 10.5–13.5 seconds				
>1.5xULN	0/220	2/219 (0.9)	3/792 (0.4)	5/751 (0.7)

EZ=ezetimibe 10 mg; All Statins=all doses of all statins; ULN=upper limit of reference range.

Note: These data are presented in the form X/Y, where X represents the number of subjects who met the criterion for a value outside prespecified limits as indicated, and Y represents the number of subjects who had at least one postbaseline observation for the test in question.

APPEARS THIS WAY
ON ORIGINAL

Table 69 Primary Hypercholesterolemia
Factorial Coadministration Pool
Hematology: Platelet Count, White Blood Cell (WBC) Count, Hemoglobin, Hematocrit, And Prothrombin Time
Mean and Median Changes from Baseline To Endpoint

Values	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
Platelet Count; Reference Range: 150–450 x 10^9/L				
Baseline Value (x 10^9/L)				
Mean	256	253	258	261
(SD, n)	(60, 259)	(56.7, 262)	(60.8, 935)	(59.3, 925)
Median	251	247	253	257
Change from Baseline to Endpoint (x 10^9/L)				
Mean	4.89	3.9	-2.29	-6.33
(SD, n)	(30.7, 248)	(31.2, 251)	(34.2, 905)	(37.1, 888)
Median	3	3	-4	-6
White Blood Cell Count; Reference Range: 4.8–10.8 x 10^9/L				
Baseline Value (x 10^9/L)				
Mean	5.74	5.75	5.91	5.86
(SD, n)	(1.55, 259)	(1.64, 262)	(1.69, 936)	(1.58, 925)
Median	5.5	5.5	5.7	5.6
Change from Baseline to Endpoint (x 10^9/L)				
Mean	0.136	0.172	0.229	0.323
(SD, n)	(1.15, 248)	(1.15, 251)	(1.25, 906)	(1.28, 888)
Median	0.15	0.1	0.2	0.3
Hemoglobin; Reference Range: Female 12–16 g/dL; Male 14–18 g/dL				
Baseline Value (g/dL)				
Mean	14.2	14.2	14.2	14.2
(SD, n)	(1.33, 259)	(1.16, 262)	(1.28, 936)	(1.24, 925)
Median	14.1	14.3	14.1	14.1
Change from Baseline to Endpoint (g/dL)				
Mean	0.0008	-0.011	-0.09	-0.097
(SD, n)	(0.619, 248)	(0.648, 251)	(0.643, 906)	(0.617, 888)
Median	0	0	-0.1	-0.1

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Table 69 Completed.

Values	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
Hematocrit; Reference Range: Female 36%–46%; Male 42%–54%				
Baseline Value				
Mean	41.9	42.1	42	42
(SD, n)	(3.84, 259)	(3.45, 262)	(3.73, 936)	(3.57, 925)
Median	41.8	42	41.8	41.9
Change from Baseline to Endpoint				
Mean	0.067	0.022	-0.214	-0.198
(SD, n)	(1.99, 248)	(2.03, 251)	(2.05, 906)	(1.94, 888)
Median	0.25	0	-0.1	-0.1
Prothrombin Time; Reference Range: 10.5–13.5 seconds				
Baseline Value (sec)				
Mean	11.6	11.8	11.7	11.6
(SD, n)	(0.706, 242)	(1.31, 236)	(2.86, 862)	(0.773, 833)
Median	11.5	11.6	11.5	11.6
Change from Baseline to Endpoint (sec)				
Mean	0.138	0.105	0.13	0.302
(SD, n)	(0.773, 205)	(1.22, 197)	(0.898, 727)	(3.77, 684)
Median	0	0	0.1	0.1

EZ=ezetimibe 10 mg; All Statins=all doses of all statins; (SD, n) = standard deviation, number of subjects included in calculation of change.

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Table 70 Primary Hypercholesterolemia
Factorial Coadministration Pool
Allergic Reaction/Rash Adverse Events (AEs)

Number And Percent Of Patients

Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
ANY ALLERGIC REACTION / RASH ADVERSE EVENT	**6 (2.3)**	**16 (6.1)**	**48 (5.1)**	**49 (5.3)**
ALLERGIC REACTION	0	0	2 (0.2)	1 (0.1)
ALLERGY	3 (1.2)	4 (1.5)	13 (1.4)	16 (1.7)
ALLERGY AGGRAVATED	1 (0.4)	1 (0.4)	8 (0.9)	3 (0.3)
DERMATITIS	0	0	0	2 (0.2)
EOSINOPHILIA	0	1 (0.4)	0	0
FACE EDEMA	0	0	1 (0.1)	1 (0.1)
PHOTOSENSITIVITY REACTION	0	0	0	1 (0.1)
PRURITUS	2 (0.8)	2 (0.8)	10 (1.1)	5 (0.5)
RASH	0	3 (1.1)	10 (1.1)	14 (1.5)
RASH AGGRAVATED	0	0	1 (0.1)	0
RASH ERYTHEMATOUS	0	1 (0.4)	0	0
RASH MACULOPAPULAR	0	1 (0.4)	0	0
RASH VESICULAR	0	0	1 (0.1)	0
SKIN DISORDER	0	1 (0.4)	1 (0.1)	4 (0.4)
URTICARIA	0	2 (0.8)	2 (0.2)	4 (0.4)

EZ=ezetimibe 10 mg; All Statins=all doses of all statins.

Table 71 Primary Hypercholesterolemia
Factorial Coadministration Pool
Central and Peripheral Nervous System Adverse Events (AEs)

Number And (Percent) Of Patients

Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
ANY CNS/PNS ADVERSE EVENT	**12 (4.6)**	**10 (3.8)**	**51 (5.4)**	**34 (3.7)**
ATAXIA	1 (0.4)	0	0	0
CEREBROVASCULAR ACCIDENT NOS	1 (0.4)	0	0	0
CEREBROVASCULAR DISORDER	0	0	0	1 (0.1)
CONFUSION	0	0	0	1 (0.1)
DYSPHASIA	0	0	1 (0.1)	0
DYSPHONIA	1 (0.4)	0	0	0
GAIT ABNORMAL	0	0	0	1 (0.1)
HYPERTONIA	0	2 (0.8)	8 (0.9)	7 (0.8)
HYPOESTHESIA	3 (1.2)	2 (0.8)	5 (0.5)	6 (0.6)
HYPOREFLEXIA	0	0	1 (0.1)	0
LOSS OF CONSCIOUSNESS	0	1 (0.4)	0	0
MIGRAINE	3 (1.2)	0	16 (1.7)	9 (1.0)
MIGRAINE AGGRAVATED	0	0	1 (0.1)	0
NEURALGIA	0	3 (1.1)	2 (0.2)	4 (0.4)
PARESTHESIA	3 (1.2)	1 (0.4)	8 (0.9)	4 (0.4)
RESTLESS LEG SYNDROME	0	0	0	1 (0.1)
SOMNOLENCE	0	1 (0.4)	4 (0.4)	1 (0.1)
SPEECH DISORDER	0	0	1 (0.1)	0
TRANSIENT ISCHEMIC ATTACK	0	0	1 (0.1)	0
TREMOR	0	0	3 (0.3)	1 (0.1)
TWITCHING	1 (0.4)	0	1 (0.1)	0
TWITCHING AGGRAVATED	0	0	1 (0.1)	0

EZ=ezetimibe 10 mg; All Statins=all doses of all statins; CNS=central nervous system; PNS=peripheral nervous system; NOS=not otherwise specified.

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Table 72 Primary Hypercholesterolemia
Factorial Coadministration Pool
Psychiatric Adverse Events (AEs)

Number And (Percent) Of Patients

Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
ANY PSYCHIATRIC ADVERSE EVENT	**9 (3.5)**	**7 (2.7)**	**36 (3.8)**	**28 (3.0)**
AMNESIA	1 (0.4)	0	0	0
ANXIETY	0	3 (1.1)	9 (1.0)	5 (0.5)
ANXIETY AGGRAVATED	0	0	1 (0.1)	0
BEHAVIOR DISORDER	0	0	1 (0.1)	0
DEPRESSION	1 (0.4)	1 (0.4)	3 (0.3)	3 (0.3)
DEPRESSION WORSENED	1 (0.4)	0	1 (0.1)	0
EMOTIONAL LABILITY	0	1 (0.4)	0	1 (0.1)
EUPHORIA	0	0	0	1 (0.1)
IMPOTENCE	0	1 (0.9)	3 (0.8)	0
INSOMNIA	6 (2.3)	3 (1.1)	16 (1.7)	16 (1.7)
LIBIDO DECREASED	0	0	2 (0.2)	1 (0.1)
MANIC REACTION	0	0	1 (0.1)	0
NERVOUSNESS	0	0	1 (0.1)	3 (0.3)
PARONIRIA	1 (0.4)	0	0	1 (0.1)

EZ=ezetimibe 10 mg; All Statins=all doses of all statins.

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Table 73 Primary Hypercholesterolemia
Factorial Coadministration Pool
Gastrointestinal Adverse Events (AEs)

Number And (Percent) Of Patients

Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
ANY GASTROINTESTINAL ADVERSE EVENT	**47 (18.1)**	**54 (20.6)**	**171 (18.3)**	**155 (16.8)**
ABDOMINAL DISTENSION	2 (0.8)	4 (1.5)	2 (0.2)	6 (0.6)
ABDOMINAL PAIN	6 (2.3)	7 (2.7)	29 (3.1)	32 (3.5)
ABDOMINAL TENDERNESS	1 (0.4)	1 (0.4)	0	1 (0.1)
ANAL STENOSIS	0	0	0	1 (0.1)
BLOOD IN STOOL	0	0	2 (0.2)	1 (0.1)
BOWEL SOUNDS ABNORMAL	0	1 (0.4)	0	0
CHANGE IN BOWEL HABIT (NOS)	1 (0.4)	0	0	0
CHEILITIS	0	0	0	2 (0.2)
COLITIS	1 (0.4)	0	1 (0.1)	1 (0.1)
COLITIS ULCERATIVE	0	0	0	1 (0.1)
COLONIC POLYP	1 (0.4)	0	2 (0.2)	1 (0.1)
CONSTIPATION	6 (2.3)	8 (3.1)	18 (1.9)	10 (1.1)
CONSTIPATION AGGRAVATED	0	0	0	2 (0.2)
DEFECATION URGENCY	0	0	0	1 (0.1)
DIARRHEA	4 (1.5)	9 (3.4)	27 (2.9)	26 (2.8)
DISEASES OF ESOPHAGUS	0	0	0	1 (0.1)
DIVERTICULITIS	0	0	2 (0.2)	1 (0.1)
DIVERTICULITIS AGGRAVATED	0	0	0	1 (0.1)
DIVERTICULOSIS	0	2 (0.8)	1 (0.1)	1 (0.1)
DYSPEPSIA	6 (2.3)	8 (3.1)	24 (2.6)	16 (1.7)
DYSPHAGIA	0	0	1 (0.1)	1 (0.1)
ESOPHAGALGIA	0	0	1 (0.1)	0
ESOPHAGOSPASM	0	0	0	1 (0.1)
FECAL INCONTINENCE	0	0	0	2 (0.2)
FECAL OCCULT BLOOD POSITIVE	1 (0.4)	1 (0.4)	2 (0.2)	4 (0.4)
FECES DISCOLORED	0	0	2 (0.2)	0
FLATULENCE	2 (0.8)	2 (0.8)	6 (0.6)	12 (1.3)
FREQUENT BOWEL MOVEMENTS	0	0	2 (0.2)	3 (0.3)
GASTRITIS	0	1 (0.4)	1 (0.1)	4 (0.4)
GASTRO-INTESTINAL DISORDER NOS	0	0	0	1 (0.1)
GASTROENTERITIS	2 (0.8)	3 (1.1)	11 (1.2)	3 (0.3)
GASTROESOPHAGEAL REFLUX	0	2 (0.8)	6 (0.6)	2 (0.2)
GASTROESOPHAGEAL REFLUX AGGRAVATED	0	1 (0.4)	2 (0.2)	0
GI HEMORRHAGE	1 (0.4)	0	0	0
GINGIVAL BLEEDING	1 (0.4)	0	1 (0.1)	1 (0.1)
GINGIVAL PAIN	0	1 (0.4)	0	0
GINGIVITIS	0	0	0	4 (0.4)
HEMORRHOIDAL BLEEDING	0	0	1 (0.1)	1 (0.1)
HEMORRHOIDS	1 (0.4)	2 (0.8)	3 (0.3)	1 (0.1)
HIATAL HERNIA AGGRAVATED	1 (0.4)	0	0	0
HIATUS HERNIA	0	1 (0.4)	0	0
ILEITIS	0	1 (0.4)	0	0
ILEUS	0	0	1 (0.1)	0
ILEUS PARALYTIC	0	0	0	1 (0.1)
IRRITABLE BOWEL SYNDROME	0	0	1 (0.1)	0
IRRITABLE BOWEL SYNDROME AGGRAVATED	0	1 (0.4)	0	0
LOOSE STOOLS	1 (0.4)	1 (0.4)	6 (0.6)	6 (0.6)
MELENA	0	0	0	1 (0.1)
MOUTH DRY	2 (0.8)	1 (0.4)	2 (0.2)	2 (0.2)
MOUTH ULCERATION	2 (0.8)	0	0	0

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Table 73 Completed.

Number And (Percent) Of Patients

Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
NAUSEA	12 (4.6)	8 (3.1)	47 (5.0)	33 (3.6)
ORAL PAIN	0	0	1 (0.1)	0
PERIODONTITIS	0	0	0	1 (0.1)
RECTAL BLEEDING	0	0	2 (0.2)	0
RETCHING	0	0	1 (0.1)	1 (0.1)
RUQ PAIN	0	1 (0.4)	2 (0.2)	3 (0.3)
STOMATITIS	0	0	1 (0.1)	0
STOMATITIS ULCERATIVE	0	0	0	2 (0.2)
STOOL ABNORMAL	0	0	1 (0.1)	2 (0.2)
TOOTH CARIES	0	0	1 (0.1)	2 (0.2)
TOOTH DISORDER	0	1 (0.4)	2 (0.2)	4 (0.4)
TOOTHACHE	2 (0.8)	3 (1.1)	9 (1.0)	8 (0.9)
VOMITING	1 (0.4)	3 (1.1)	16 (1.7)	15 (1.6)

EZ=ezetimibe 10 mg; All Statins=all doses of all statins; NOS = not otherwise specified.

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Table 74 Primary Hypercholesterolemia
Factorial Coadministration Pool
Gallbladder-related Adverse Events (AEs)

Number And (Percent) Of Patients

Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
ANY GALLBLADDER-RELATED ADVERSE EVENT	**0**	**0**	**2 (0.2)**	**0**
CHOLECYSTECTOMY	0	0	2 (0.2)	0
CHOLECYSTITIS	0	0	1 (0.1)	0
CHOLELITHIASIS	0	0	1 (0.1)	0

EZ=Ezetimibe 10 mg; All Statins=all doses of all statins.

Table 75 Primary Hypercholesterolemia Factorial Coadministration Pool Liver and Biliary System Adverse Events (AEs)

Number And (Percent) Of Patients

Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
TREATMENT-EMERGENT LIVER AND BILIARY SYSTEM DISORDERS	**4 (1.5)**	**5 (1.9)**	**23 (2.5)**	**53 (5.7)**
BILIRUBINEMIA	0	0	0	1 (0.1)
CHOLECYSTITIS	0	0	1 (0.1)	0
CHOLELITHIASIS	0	0	1 (0.1)	0
CHOLESTASIS	0	0	1 (0.1)	0
GAMMA-GT INCREASED	1 (0.4)	4 (1.5)	7 (0.7)	15 (1.6)
HEPATIC ENZYMES INCREASED	1 (0.4)	1 (0.4)	9 (1.0)	13 (1.4)
HEPATOMEGALY	0	0	1 (0.1)	0
LIVER FATTY	0	0	0	1 (0.1)
SGOT INCREASED	1 (0.4)	1 (0.4)	3 (0.3)	26 (2.8)
SGPT INCREASED	2 (0.8)	3 (1.1)	7 (0.7)	30 (3.2)
POOL[a]: TREATMENT-EMERGENT HEPATIC ENZYMES INCREASED, SGOT INCREASED, SGPT INCREASED	**3 (1.2)**	**4 (1.5)**	**16 (1.7)**	**47 (5.1)**
POOL[a]: TREATMENT RELATED, TREATMENT EMERGENT	**1 (0.4)**	**3 (1.1)**	**14 (1.5)**	**38 (4.1)**
POOL[a]: SERIOUS[b]	**1 (0.4)**	**1 (0.4)**	**1 (0.1)**	**8 (0.9)**
POOL[a]: DISCONTINUATION[b]	**1 (0.4)**	**2 (0.8)**	**3 (0.3)**	**10 (1.1)**

a: The "pool" comprises the three terms within the boxed outlines above.

b: Phase III protocols stipulated that ALT/AST at least three time the upper limit of the reference range on two consecutive occasions at least 1 week apart should be considered a serious adverse event and result in discontinuation.

EZ = ezetimibe 10 mg; All Statins=all doses of all statins.

Note: SGOT = AST; SGPT = ALT.

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Table 76 Primary Hypercholesterolemia
Factorial Coadministration Pool
Liver Function: Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST)
Postbaseline Values Above Upper Limits of Normal (ULN)

Number And (Percent) Of Patients

High Ranges[a]	Placebo n=259	Ezetimibe n=262	All Statins n=936	Ezetimibe + All Statins n=925
Alanine Aminotransferase (ALT); Reference Range: 5–25 mU/mL				
2xULN to <3xULN	6/255 (2.4)	4/259 (1.5)	20/929 (2.2)	38/917 (4.1)
≥3xULN	0/255	2/259 (0.8)	8/929 (0.9)	18/917 (2.0)
≥3xULN, consecutive[b,c]	0/255	0/259	4/929 (0.4)	12/917 (1.3)
≥5xULN[b]	0/255	1/259 (0.4)	0/929	6/917 (0.7)
≥10xULN[b]	0/255	0/259	0/929	0/917
Aspartate Aminotransferase (AST); Reference Range: 8–22 mU/mL				
2xULN to <3xULN	2/255 (0.8)	3/259 (1.2)	8/929 (0.9)	24/917 (2.6)
≥3xULN	0/255	1/259 (0.4)	6/929 (0.6)	8/917 (0.9)
≥3xULN, consecutive[b,c]	0/255	0/259	3/929 (0.3)	5/917 (0.5)
≥5xULN[b]	0/255	0/259	1/929 (0.1)	4/917 (0.4)
≥10xULN[b]	0/255	0/259	0/929	0/917
ALT and/or AST				
≥3xULN	0/255	2/259 (0.8)	9/929 (1.0)	19/917 (2.1)
≥3xULN, consecutive[b,c]	0/255	0/259	4/929 (0.4)	13/917 (1.4)
≥5xULN[b]	0/255	1/259 (0.4)	1/929 (0.1)	6/917 (0.7)
≥10xULN[b]	0/255	0/259	0/929	0/917

a: Subjects appear in category of maximum value.

b: This is a subset of ≥3xULN.

c: Consecutive is defined as follows: (1) two or more consecutive values ≥3xULN in the subject's record; (2) last value in subject's record is ≥3xULN (presumed consecutive); or (3) a value ≥3xULN during treatment or ≤2 days after the end of treatment is followed by a value <3xULN, but the sample for the second value was collected more than 2 days after the subject's last day of dosing (presumed consecutive).

EZ=ezetimibe 10 mg; All Statins=all doses of all statins; ULN=upper limit of the reference range.

NOTE: The entries in the form X/Y correspond to the number of subjects who met the criterion for a high value (X) / the number of subjects who had at least one postbaseline observation for the test in question (Y).

Table 77 Primary Hypercholesterolemia
Factorial Coadministration Pool
Liver Function: Alanine Aminotransferase (ALT) And Aspartate Aminotransferase (AST)
Postbaseline Consecutive Values ≥3x Upper Limits Of Normal (ULN), By Statin Dose And Type

Number And (Percent) Of Patients

Test	Placebo	Ezetimibe 10 mg	Statin 10 mg	EZ + Statin 10	Statin 20 mg	EZ + Statin 20	Statin 40 mg	EZ + Statin 40	Statin 80 mg	EZ + Statin 80
Atorvastatin (Protocol P00692)										
ALT	0/60	0/65	0/60	1/65 (2)	0/60	1/62 (2)	0/64	2/64 (3)	1/62 (2)	0/62
AST	0/60	0/65	0/60	1/65 (2)	0/60	0/62	0/64	1/64 (2)	1/62 (2)	0/62
ALT and/or AST	0/60	0/65	0/60	1/65 (2)	0/60	1/62 (2)	0/64	2/64 (3)	1/62 (2)	0/62
Simvastatin (Protocol P00690)										
ALT	0/69	0/69	0/70	0/67	1/61 (2)	1/58 (1)	0/64	4/72 (6)	1/66 (2)	1/62 (2)
AST	0/69	0/69	0/70	0/67	1/61 (2)	0/58	0/64	2/72 (3)	0/66	0/62
ALT and/or AST	0/69	0/69	0/70	1/67	1/61 (2)	1/58 (1)	0/64	4/72 (6)	1/66 (2)	1/62 (2)
Pravastatin (Protocol P00691)										
ALT	0/63	0/63	0/66	0/71	0/69	0/66	1/69 (1)	1/67 (1)	--	--
AST	0/63	0/63	0/66	0/71	0/69	1/66 (2)	1/69 (1)	0/67	--	--
ALT and/or AST	0/63	0/63	0/66	0/71	0/69	1/66 (2)	1/69 (1)	1/67 (1)	--	--
Lovastatin (Protocol P00679)										
ALT	0/63	0/71	0/73	1/64 (2)	0/72	0/62	0/73	0/65	--	--
AST	0/63	0/71	0/73	0/64	0/72	0/62	0/73	0/65	--	--
ALT and/or AST	0/63	0/71	0/73	1/64 (2)	0/72	0/62	0/73	0/65	--	--
Pooled Over All Four Protocols										
ALT	0/255	0/259	0/269	2/267 (0.7)	1/262 (0.4)	2/258 (0.8)	1/270 (0.4)	7/268 (2.6)	2/128 (1.6)	1/124 (0.8)
AST	0/255	0/259	0/269	1/267 (0.4)	1/262 (0.4)	1/258 (0.4)	1/270 (0.4)	3/268 (1.1)	1/128 (0.8)	0/124
ALT and/or AST	0/255	0/259	0/269	2/267 (0.7)	1/262 (0.4)	3/258 (1.2)	1/270 (0.4)	7/268 (2.6)	2/128 (1.6)	1/124 (0.8)

-- = not administered; EZ = ezetimibe 10 mg; Statins XX = dose of statin in milligrams.

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Table 78 Primary Hypercholesterolemia
Factorial Coadministration Pool
Liver Function: Alanine Aminotransferase (ALT)
Baseline To Endpoint and Maximum Postbaseline Changes In Values

Number of Patients

	Baseline		Postbaseline Grade[a,b]			
	Grade[a]	Number	0	1	2	3
Endpoint Grade						
Placebo	0	219	207	12	0	0
(no. subjects with a baseline value	1	31	15	15	1	0
and an endpoint value = 253)	2	2	1	0	1	0
	3	1	1	0	0	0
Ezetimibe 10 mg	0	228	208	20	0	0
(no. subjects with a baseline value	1	25	6	17	2	0
and an endpoint value = 254)	2	1	0	0	1	0
	3	0	0	0	0	0
All Statins	0	820	732	77	8	3
(no. subjects with a baseline value	1	98	35	60	2	1
and an endpoint value = 920)	2	2	2	0	0	0
	3	0	0	0	0	0
EZ + All Statins	0	811	666	133	8	4
(no. subjects with a baseline value	1	88	21	53	9	5
and an endpoint value = 908)	2	9	2	2	3	2
	3	0	0	0	0	0
Maximum Postbaseline Grade						
Placebo	0	221	197	23	1	0
(no. subjects with a baseline value	1	31	9	18	4	0
and at least one other value any	2	2	1	0	1	0
time after baseline = 255)	3	1	1	0	0	0
Ezetimibe 10 mg	0	231	186	43	1	1
(no. subjects with a baseline value	1	27	2	22	2	1
and at least one other value any	2	1	0	0	1	0
time after baseline = 259)	3	0	0	0	0	0
All Statins	0	829	656	154	12	7
(no. subjects with a baseline value	1	98	12	77	8	1
and at least one other value any	2	2	1	1	0	0
time after baseline = 929)	3	0	0	0	0	0
EZ + All Statins	0	820	567	228	19	6
(no. subjects with a baseline value	1	88	6	59	13	10
and at least one other value any	2	9	0	1	6	2
time after baseline = 917)	3	0	0	0	0	0

a: Grade 0 = <1xULN; Grade 1 = 1 to <2xULN; Grade 2 = 2 to <3xULN; Grade 3 = ≥3xULN.
b: Boxed cells indicate an increase from baseline in grade.
ULN = upper limit of the reference range. Reference range = 5-25 mU/mL.

Table 79 Primary Hypercholesterolemia
Factorial Coadministration Pool
Liver Function: Gamma-Glutamyl Transpeptidase (GGT), Alkaline Phosphatase, and Total Bilirubin
Postbaseline Values Above Upper Limits Of Normal (ULN)

Number And (Percent) Of Patients

High Ranges[a]	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
Gamma-Glutamyl Transpeptidase (GGT); Reference Range: 5–29 mU/mL				
2xULN to <3xULN	9/255 (3.5)	15/259 (5.8)	45/929 (4.8)	45/917 (4.9)
≥3xULN	3/255 (1.2)	9/259 (3.5)	26/929 (2.8)	33/917 (3.6)
Alkaline Phosphatase; Reference Range: 32–72 mU/mL				
2xULN to <3xULN	0/255	0/259	1/929 (0.1)	2/917 (0.2)
≥3xULN	0/255	0/259	2/929 (0.2)	1/917 (0.1)
Total Bilirubin; Reference Range: 0.1–1.1 mg/dL				
2xULN to <3xULN	0/255	0/259	3/929 (0.3)	3/917 (0.3)
≥3xULN	0/255	0/259	0/929	0/917

a: Subjects appear in category of maximum value.

EZ=ezetimibe 10 mg; All Statins=all doses of all statins.

Note: These data are presented in the form X/Y, where X represents the number of subjects who met the criterion for a high value as indicated, and Y represents the number of subjects who had at least one postbaseline observation for the test in question.

Table 80 Primary Hypercholesterolemia
Factorial Coadministration Pool
Increased Creatine Phosphokinase (CPK)
Reported As Adverse Events (AEs)

Number And (Percent) Of Patients

Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
TREATMENT-EMERGENT ADVERSE EVENT	5 (1.9)	4 (1.5)	12 (1.3)	14 (1.5)
TREATMENT-RELATED, TREATMENT-EMERGENT ADVERSE EVENT	2 (0.8)	2 (0.8)	6 (0.6)	7 (0.8)
SERIOUS ADVERSE EVENT	1 (0.4)	0	0	1 (0.1)
ADVERSE EVENT CAUSING DISCONTINUATION	2 (0.8)	0	1 (0.1)	4 (0.4)

Table 81 Primary Hypercholesterolemia
Factorial Coadministration Pool
Creatine Phosphokinase (CPK)
Postbaseline Values Above Upper Limit Of Normal (ULN)

Number And (Percent) Of Patients

High Ranges[a]	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
3xULN to <5xULN	3/255 (1.2)	3/259 (1.2)	15/929 (1.6)	10/917 (1.1)
5xULN to <10xULN	0/255	3/259 (1.2)	6/929 (0.6)	4/917 (0.4)
≥10xULN	0/255	0/259	4/929 (0.4)	0[b]/917

a: Subjects appear only in the category of maximum value; the reference range (0-120 mU/mL).

b: Subject 1311 at Center 22 in Protocol P00692 fulfilled the criteria, but was not included in the data base because the samples were analyzed at a local laboratory. The correct entry should be "1/917 (0.1)."

EZ=Ezetimibe 10 mg; All Statins=all doses of all statins.

Note: These data are presented in the form X/Y, where X represents the number of subjects who met the criterion for a high value as indicated, and Y represents the number of subjects who had at least one postbaseline observation for the test in question.

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Table 82 Primary Hypercholesterolemia
Factorial Coadministration Pool
Creatine Phosphokinase (CPK)
Postbaseline Values Above Upper Limit Of Normal (ULN), With Associated Muscle Symptoms

Number And (Percent) Of Patients

Event of Interest[a]	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
≥10xULN[b] With Muscle Symptoms[c]	0/255	0/259	1/929 (0.1)	0[d]/917
≥10xULN	0/255	0/259	4/929 (0.4)	0[d]/917
5xULN to <10xULN With Muscle Symptoms	0/255	2/259 (0.8)	0/929	1/917 (0.1)

a: The third row is mutually exclusive of the first and second rows; a subject appears only in the category of greatest CPK value during treatment. The first row is a subset of the second row.

b: ULN = upper limit of the reference range (0-120 mU/mL).

c: "Muscle symptoms" comprise a predefined list of symptoms that could potentially indicate drug-induced muscle damage and that were recorded as present within 7 days before or after the observed high CPK value.

d: Subject 1311 at Center 22 in Protocol P00692, who received ezetimibe 10 mg and atorvastatin 40 mg, fulfilled the criteria, but was not included in the data base because the samples were analyzed at a local laboratory. The correct entry should be "1/917 (0.1)."

EZ=ezetimibe 10 mg; All Statins=all doses of all statins.

NOTE: The entries in the form X/Y correspond to the number of subjects who met the criterion for a high value (X) / the number of subjects who had at least one postbaseline observation for the test in question (Y).

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Table 83 Primary Hypercholesterolemia
Factorial Coadministration Pool
Postbaseline Values And Changes From Baseline In Pulse, Systolic Blood Pressure, Diastolic Blood Pressure, And Body Weight

Number And (Percent) Of Patients

Value/Change	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
Pulse (bpm)				
Value <60	20/251 (8.0)	14/257 (5.4)	71/924 (7.7)	81/913 (8.9)
Value >100	0/251	0/257	2/924 (0.2)	2/913 (0.2)
Decrease >20	4/249 (1.6)	3/255 (1.2)	8/920 (0.9)	12/911 (1.3)
Increase >20	5/249 (2.0)	5/255 (2.0)	18/920 (2.0)	11/911 (1.2)
Systolic Blood Pressure (mm Hg)				
Value >150	12/251 (4.8)	10/257 (3.9)	58/925 (6.3)	60/913 (6.6)
Decrease >20	18/249 (7.2)	24/256 (9.4)	82/922 (8.9)	89/911 (9.8)
Increase >20	8/249 (3.2)	5/256 (2.0)	48/922 (5.2)	40/911 (4.4)
Diastolic Blood Pressure (mm Hg)				
Value >100	1/251 (0.4)	0/257	2/925 (0.2)	6/913 (0.7)
Decrease >20	2/249 (0.8)	10/256 (3.9)	13/922 (1.4)	22/911 (2.4)
Increase >20	3/249 (1.2)	2/256 (0.8)	3/922 (0.3)	5/911 (0.5)
Body Weight (kg)				
Decrease ≥3	26/255 (10.2)	19/258 (7.4)	67/928 (7.2)	67/917 (7.3)
Increase ≥3	26/255 (10.2)	17/258 (6.6)	77/928 (8.3)	72/917 (7.9)

EZ=ezetimibe 10 mg; All Statins=all doses of all statins.

NOTE: These data are presented in the form X/Y, where X represents the number of subjects who met the criterion for a value outside prespecified limits as indicated, and Y represents the number of subjects who had at least one postbaseline observation for the test in question.

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Table 84 Primary Hypercholesterolemia
Factorial Coadministration Pool
Changes From Baseline In Electrocardiograms

Number And (Percent) Of Patients

At Last Observation	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
Normal at Baseline	(n=125)	(n=126)	(n=456)	(n=436)
Clinically Significant Change	0	0	3 (0.7)	3 (0.7)
Change, but Not Clinically Significant	27 (21.6)	28 (22.2)	87 (19.1)	91 (20.9)
No Change	94 (75.2)	96 (76.2)	347 (76.1)	325 (74.5)
Missing	4 (3.2)	2 (1.6)	19 (4.2)	17 (3.9)
Abnormal at Baseline	(n=134)	(n=133)	(n=480)	(n=488)
Clinically Significant Change	1 (0.7)	1 (0.8)	4 (0.8)	3 (0.6)
Change, but Not Clinically Significant	65 (48.5)	64 (48.1)	234 (48.8)	225 (46.1)
No Change	60 (44.8)	66 (49.6)	226 (47.1)	243 (49.8)
Missing	8 (6.0)	2 (1.5)	16 (3.3)	17 (3.5)
Change From Baseline Not Evaluable[a]	(n=0)	(n=3)	(n=0)	(n=1)

a: Subject was missing results at Baseline.

EZ=ezetimibe 10 mg; All Statins=all doses of all statins.

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Table 85 Primary Hypercholesterolemia/Patients With Documented CHD, Diabetes Mellitus, Or CVD Risk Factors Ezetimibe Added To An Established Statin Serious Adverse Events (AEs)

Body System/Organ Class and Adverse Event	Number And (Percent) Of Patients: Statin + Placebo (n=390)	Statin + Ezetimibe 10 (n=379)
ANY SERIOUS ADVERSE EVENT	**9 (2)**	**19 (5)**
BENIGN AND MALIGNANT NEOPLASMS (INCLUDING CYSTS AND POLYPS)	**2 (<1)**	**2 (<1)**
BASAL CELL CARCINOMA	1 (<1)	1 (<1)
BREAST NEOPLASM MALIGNANT FEMALE	0	1 (<1)
PROSTATIC CANCER	1 (<1)	0
BODY AS A WHOLE—GENERAL DISORDERS	**1 (<1)**	**2 (<1)**
CHEST PAIN	1 (<1)	2 (<1)
CARDIOVASCULAR DISORDERS, GENERAL	**1 (<1)**	**6 (2)**
ANGINA PECTORIS	0	4 (1)
ANGINA PECTORIS AGGRAVATED	0	1 (<1)
CORONARY ARTERY DISORDER	0	2 (<1)
CORONARY ARTERY DISORDER AGGRAVATED	1 (<1)	0
CENTR AND PERIPH NERV SYST DISORDERS	**1 (<1)**	**1 (<1)**
CEREBRAL ISCHEMIA	1 (<1)	0
CONVULSIONS	0	1 (<1)
DISORDERS OF THE EAR & LABYRINTH	**1 (<1)**	**0**
VERTIGO	1 (<1)	0
DISORDERS OF THE IMMUNE SYSTEM	**0**	**1 (<1)**
ALLERGIC REACTION	0	1 (<1)
GASTROINTESTINAL SYSTEM DISORDERS	**0**	**6 (2)**
ABDOMINAL PAIN	0	2 (<1)
APPENDICITIS PERFORATED	0	1 (<1)
GASTRITIS	0	1 (<1)
GASTROENTERITIS	0	1 (<1)
GASTROESOPHAGEAL REFLUX AGGRAVATED	0	1 (<1)
HIATUS HERNIA	0	1 (<1)
INTESTINAL OBSTRUCTION	0	1 (<1)
INFECTION AND INFESTATIONS	**0**	**1 (<1)**
ABDOMINAL ABSCESS	0	1 (<1)
INJURY AND POISONING	**0**	**1 (<1)**
FRACTURE, BONE	0	1 (<1)
MUSCULOSKELETAL SYSTEM DISORDERS	**2 (<1)**	**0**
CARTILAGE INJURY	1 (<1)	0
INTERVERTEBRAL DISC DISORDER NOS	1 (<1)	0
RESPIRATORY SYSTEM DISORDERS	**1 (<1)**	**1 (<1)**
BRONCHITIS	1 (<1)	0
HEMOPTYSIS	0	1 (<1)

Table 86 Primary Hypercholesterolemia/Patients With Documented CHD, Diabetes Mellitus, Or CVD Risk Factors Ezetimibe Added To An Established Statin Discontinuations Due To Adverse Events (AEs)

	Number And (Percent) Of Patients	
Body System/Organ Class and Adverse Event	Statin + Placebo (n=390)	Statin + Ezetimibe † (n=379)
ANY ADVERSE EVENT	**13 (3)**	**12 (3)**
BODY AS A WHOLE—GENERAL DISORDERS	**1 (<1)**	**5 (1)**
CHEST PAIN	1 (<1)	0
DIZZINESS	0	1 (<1)
FATIGUE	0	2 (<1)
HEADACHE	0	3 (<1)
UNEXPECTED THERAPEUTIC EFFECT	0	1 (<1)
CARDIOVASCULAR DISORDERS, GENERAL	**0**	**3 (<1)**
ANGINA PECTORIS	0	2 (<1)
ANGINA PECTORIS AGGRAVATED	0	1 (<1)
CORONARY ARTERY DISORDER	0	1 (<1)
DISORDERS OF THE EAR AND LABYRINTH	**1 (<1)**	**0**
VERTIGO	1 (<1)	0
GASTROINTESTINAL SYSTEM DISORDERS	**5 (1)**	**5 (1)**
ABDOMINAL PAIN	3 (<1)	1 (<1)
CONSTIPATION	0	1 (<1)
DEFECATION URGENCY	0	1 (<1)
DIARRHEA	1 (<1)	1 (<1)
DYSPEPSIA	2 (<1)	0
INTESTINAL OBSTRUCTION	0	1 (<1)
NAUSEA	1 (<1)	3 (<1)
RECTAL PAIN	0	1 (<1)
LIVER AND BILIARY SYSTEM DISORDERS[a]	1 (<1)	1 (<1)
SGOT INCREASED	1 (<1)	1 (<1)
SGPT INCREASED	1 (<1)	1 (<1)
METABOLIC AND NUTRITIONAL DISORDERS	2 (<1)	0
CREATINE PHOSPHOKINASE INCREASED	1 (<1)	0
HYPERKALEMIA	1 (<1)	0
MUSCULOSKELETAL SYSTEM DISORDERS	2 (<1)	1 (<1)
BONE PAIN	0	1 (<1)
MUSCLE WEAKNESS	0	1 (<1)
MUSCULOSKELETAL PAIN	1 (<1)	0
MYALGIA	2 (<1)	1 (<1)
PSYCHIATRIC DISORDERS	0	1 (<1)
INSOMNIA	0	1 (<1)
RENAL AND URINARY SYSTEM DISORDERS	**0**	**1 (<1)**
OLIGURIA	0	1 (<1)
RESPIRATORY SYSTEM DISORDERS	1 (<1)	0
BRONCHITIS	1 (<1)	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (<1)	0
RASH	1 (<1)	0
RASH MACULOPAPULAR AGGRAVATED	1 (<1)	0
SURGICAL AND MEDICAL PROCEDURES	**1 (<1)**	**0**
POSTOPERATIVE HEMORRHAGE	1 (<1)	0

a: SGOT = AST; SGPT = ALT.

Table 87 Primary Hypercholesterolemia/Patients With Documented CHD, Diabetes Mellitus, Or CVD Risk Factors Ezetimibe Added To An Established Statin Adverse Events (AEs) Of Any Severity Reported For ≥2% Of Patients In Any Pooled Treatment Group

	Number And (Percent) Of Patients	
Body System/Organ Class and Adverse Event	Statin + Placebo (n=390)	Statin + Ezetimibe 10 mg (n=379)
ANY ADVERSE EVENT	**198 (51)**	**226 (60)**
BODY AS A WHOLE - GENERAL DISORDERS		
DIZZINESS	14 (4)	8 (2)
FATIGUE	11 (3)	17 (4)
HEADACHE	15 (4)	15 (4)
GASTRO-INTESTINAL SYSTEM DISORDERS		
ABDOMINAL PAIN	17 (4)	16 (4)
CONSTIPATION	8 (2)	12 (3)
DIARRHEA	8 (2)	15 (4)
DYSPEPSIA	7 (2)	9 (2)
FLATULENCE	6 (2)	14 (4)
NAUSEA	9 (2)	11 (3)
INFECTION AND INFESTATIONS		
PHARYNGITIS	8 (2)	6 (2)
SINUSITIS	5 (1)	8 (2)
UPPER RESP TRACT INFECTION	31 (8)	30 (8)
MUSCULO-SKELETAL SYSTEM DISORDERS		
ARTHRALGIA	7 (2)	14 (4)
MUSCULO-SKELETAL PAIN	8 (2)	17 (4)
MYALGIA	10 (3)	17 (4)
PSYCHIATRIC DISORDERS		
INSOMNIA	11 (3)	6 (2)

Table 88 Primary Hypercholesterolemia/Patients With Documented CHD, Diabetes Mellitus, Or CVD Risk Factors Ezetimibe Added To An Established Statin Severe or Life-Threatening Adverse Events (AEs)

Body System/Organ Class and Adverse Event	Number And (Percent) Of Patients: Statin + Placebo (n=390)	Statin + Ezetimibe 10r (n=379)
ANY ADVERSE EVENT	**12 (3)**	**20 (5)**
BENIGN AND MALIGNANT NEOPLASMS (INCLUDING CYSTS AND POLYPS)	**0**	**1 (<1)**
BREAST NEOPLASM MALIGNANT FEMALE	0	1 (<1)
BODY AS A WHOLE - GENERAL DISORDERS	**2 (<1)**	**3 (<1)**
CHEST PAIN	1 (<1)	2 (<1)
DIZZINESS	1 (<1)	0
HEADACHE	0	1 (<1)
CARDIOVASCULAR DISORDERS, GENERAL	**2 (<1)**	**4 (1)**
ANGINA PECTORIS	1 (<1)	2 (<1)
ANGINA PECTORIS AGGRAVATED	0	1 (<1)
CORONARY ARTERY DISORDER	0	2 (<1)
CORONARY ARTERY DISORDER AGGRAVATED	1 (<1)	0
CENTR AND PERIPH NERV SYST DISORDERS	**1 (<1)**	**1 (<1)**
CEREBRAL ISCHEMIA	1 (<1)	0
CONVULSIONS	0	1 (<1)
DISORDERS OF THE EAR AND LABYRINTH	**1 (<1)**	**0**
VERTIGO	1 (<1)	0
DISORDERS OF THE IMMUNE SYSTEM	**0**	**2 (<1)**
ALLERGIC REACTION	0	1 (<1)
ALLERGY AGGRAVATED	0	1 (<1)
GASTRO-INTESTINAL SYSTEM DISORDERS	**1 (<1)**	**7 (2)**
ABDOMINAL DISTENSION	0	1 (<1)
ABDOMINAL PAIN	0	1 (<1)
APPENDICITIS PERFORATED	0	1 (<1)
DIARRHEA	0	2 (<1)
DIVERTICULITIS	0	1 (<1)
DYSPEPSIA	0	1 (<1)
GASTRITIS	0	1 (<1)
GASTROENTERITIS	0	1 (<1)
INTESTINAL OBSTRUCTION	0	1 (<1)
NAUSEA	1 (<1)	0
HEART RATE AND RHYTHM DISORDERS	**1 (<1)**	**0**
ECG ABNORMAL SPECIFIC	1 (<1)	0
INFECTION AND INFESTATIONS	**0**	**2 (<1)**
ABDOMINAL ABSCESS	0	1 (<1)
UPPER RESP TRACT INFECTION	0	1 (<1)
LIVER AND BILIARY SYSTEM DISORDERS	**1 (<1)**	**0**
AST INCREASED	1 (<1)	0
ALT INCREASED	1 (<1)	0
METABOLIC AND NUTRITIONAL DISORDERS	**1 (<1)**	**0**
CREATINE PHOSPHOKINASE INCREASED	1 (<1)	0
MUSCULO-SKELETAL SYSTEM DISORDERS	**4 (1)**	**1 (<1)**
ARTHRALGIA	2 (<1)	0
ARTHRITIS	1 (<1)	0
BACK PAIN	0	1 (<1)
CARTILAGE INJURY	1 (<1)	0
INTERVERTEBRAL DISC DISORDER NOS	1 (<1)	0
RENAL AND URINARY SYSTEM DISORDERS	**0**	**1 (<1)**
BUN INCREASED	0	1 (<1)
RESPIRATORY SYSTEM DISORDERS	**2 (<1)**	**1 (<1)**
BRONCHITIS	1 (<1)	0
COUGHING	0	1 (<1)
DYSPNEA	1 (<1)	0

NOS = not otherwise specified

Table 89 Primary Hypercholesterolemia/Patients With Documented CHD, Diabetes Mellitus, Or CVD Risk Factors Ezetimibe Added To An Established Statin Blood Urea Nitrogen (BUN) And Creatinine Postbaseline Values Outside Prespecified Limits

Number And (Percent) Of Patients

High/Low Limits	Statin + Placebo (n=390)	Statin + Ezetimibe 10 mg (n=379)
Blood Urea Nitrogen; Reference Range: 5 to 20 mg/dL		
<5 mg/dL	0/386	0/374
>20 mg/dL	118/386 (30.6)	108/374 (28.9)
Creatinine; Reference Range: 0.7 to 1.4 mg/dL		
>1.4 mg/dL	25/386 (6.5)	30/374 (8.0)

Note: The entries in the form X/Y correspond to the number of subjects who met the criterion for a high or low value (X), as indicated/the number of subjects who had at least one postbaseline observation for the test in question (Y).

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Table 90 Primary Hypercholesterolemia/Patients With Documented CHD, Diabetes Mellitus, Or CVD Risk Factors Ezetimibe Added To An Established Statin Blood Urea Nitrogen (BUN) And Creatinine Mean Changes From Baseline To Endpoint

Values	Statin + Placebo (n=390)			Statin + Ezetimibe 10 mg (n=379)		
	n	Mean	(SD)	n	Mean	(SD)
Blood Urea Nitrogen; Reference Range: 5 to 20 mg/dL						
Baseline Value (mg/dL)	390	16.4	(5.0)	379	17.1	(6.1)
Change from Baseline at Endpoint	386	0.1	(3.4)	374	-0.2	(3.7)
Creatinine; Reference Range: 0.7 to 1.4 mg/dL						
Baseline Value (mg/dL)	390	1.1	(0.2)	379	1.1	(0.2)
Change from Baseline at Endpoint	386	-0.0	(0.1)	374	-0.0	(0.1)

(SD) = standard deviation.

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Table 91 Primary Hypercholesterolemia/Patients With Documented CHD, Diabetes Mellitus, Or CVD Risk Factors Ezetimibe Added To An Established Statin Hematology: Platelet Count, White Blood Cell (WBC) Count, Hemoglobin, Hematocrit, And Prothrombin Time Postbaseline Values Outside Prespecified Limits

High/Low Limits	Statin + Placebo (n=390)	Statin + Ezetimibe 10 mg (n=379)
Platelet Count; Reference Range: 150–450 x 10^9/L		
<150x10^9/L	26/386 (6.7)	30/374 (8.0)
>450x10^9/L	1/386 (0.3)	2/374 (0.5)
White Blood Cell (WBC) Count; Reference Range: 4.8–10.8 x 10^9/L		
<4.8x10^9/L	86/386 (22.3)	90/374 (24.1)
>10.8x10^9/L	13/386 (3.4)	12/374 (3.2)
Hemoglobin; Reference Range: Female 12–16 g/dL; Male 14–18 g/dL		
F:<12; M:<14 g/dL	78/386 (20.2)	107/374 (28.6)
F:>16; M:>18 g/dL	3/386 (0.8)	2/374 (0.5)
Hematocrit; Reference Range: Female 36%–46%; Male 42%–54%		
F:<36%; M:<42%	124/386 (32.1)	134/374 (35.8)
F:>46%; M:>54%	7/386 (1.8)	4/374 (1.1)
Prothrombin Time (PT); Reference Range: 10.5–13.5 seconds		
>13.5 seconds	22/353 (6.2)	23/352 (6.5)

ULN = upper limit of the reference range.

Note: The entries in the form X/Y correspond to the number of subjects who met the criterion for a high or low value (X), as indicated/the number of subjects who had at least one postbaseline observation for the test in question (Y).

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Table 92 Primary Hypercholesterolemia/Patients With Documented CHD, Diabetes Mellitus, Or CVD Risk Factors
Ezetimibe Added To An Established Statin
Liver Function: Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Gamma-Glutamyl Transpeptidase (GGT), Alkaline Phosphatase, and Total Bilirubin
Postbaseline Values Above Upper Limits of Normal (ULN)

	Number and (Percent) of Patients	
High Ranges[a]	Statin + Placebo (n=390)	Statin + Ezetimibe 10 mg (n=379)
Alanine Aminotransferase (ALT); Reference Range: 5 to 25 mU/mL		
2xULN to <3xULN	6/386 (2)	10/374 (3)
≥3xULN	0/386	5/374 (1)
Aspartate Aminotransferase (AST); Reference Range: 8 to 22 mU/mL		
2xULN to <3xULN	2/386 (<1)	5/374 (1)
≥3xULN	1/386 (<1)	2/374 (<1)
Gamma-Glutamyl Transpeptidase; Reference Range: 5 to 29 mU/mL		
2xULN to <3xULN	18/386 (5)	7/374 (2)
≥3xULN	8/386 (2)	11/374 (3)
Alkaline Phosphatase; Reference Range: 32 to 72 mU/mL		
2xULN to <3xULN	1/386 (<1)	0/374
≥3xULN	0/386	1/374 (<1)
***Total Bilirubin*; Reference Range: 0.1 to 1.1 mg/dL**		
2xULN to <3xULN	2/386 (<1)	0/374
≥3xULN	0/386	0/374

a: Subjects appear in category of maximum value.

NOTE: The entries in the form X/Y correspond to the number of subjects who met the criterion for a high value (X), as indicated/the number of subjects who had at least one postbaseline observation for the test in question (Y).

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Table 93 Primary Hypercholesterolemia/Patients With Documented CHD, Diabetes Mellitus, Or CVD Risk Factors Ezetimibe Added To An Established Statin Creatine Phosphokinase (CPK) Postbaseline Values Above Upper Limit of Normal (ULN)

	Number and (Percent) of Patients	
High Ranges[a]	Statin + Placebo (n=390)	Statin + Ezetimibe 10 mg (n=379)
3xULN to <5xULN	2/386 (<1)	4/374 (1)
5xULN to <10xULN	1/386 (<1)	2/374 (<1)
≥10xULN	1/386 (<1)	0/374

a: Subjects appear in category of maximum value.

The entries in the form X/Y correspond to the number of subjects who met the criterion for a high value (X), as indicated/the number of subjects who had at least one postbaseline observation (Y).

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Table 94 Primary Hypercholesterolemia/Patients With Documented *CHD, Diabetes Mellitus,* Or CVD Risk Factors
Ezetimibe Added To An Established Statin
Last Observation Values and Changes From Baseline In Pulse, Systolic Blood Pressure, Diastolic Blood Pressure, And Body Weight

Number and (Percent) of Patients

	Statin + Placebo (n=390)	Statin + Ezetimibe 10 mg (n=379)
Pulse (bpm) at Last Observation		
Value <60	44/386 (11.4)	51/373 (13.7)
Value >100	2/386 (0.5)	1/373 (0.3)
Decrease >20	8/384 (2.1)	7/372 (1.9)
Increase >20	4/384 (1.0)	4/372 (1.1)
Systolic Blood Pressure (mmHg) at Last Observation		
Value >150	42/386 (10.9)	27/374 (7.2)
Decrease >20	21/385 (5.5)	29/373 (7.8)
Increase >20	22/385 (5.7)	15/373 (4.0)
Diastolic Blood Pressure (mmHg) at Last Observation		
Value >100	4/386 (1.0)	3/374 (0.8)
Decrease >20	4/385 (1.0)	3/373 (0.8)
Increase >20	1/385 (0.3)	1/373 (0.3)
Body Weight (kg) at Last Observation		
Decrease ≥2	38/385 (9.9)	36/374 (9.6)
Increase ≥2	39/385 (10.1)	40/374 (10.7)
Waist Circumference (cm) at Last Observation		
Decrease ≥7	15/360 (4.2)	6/352 (1.7)
Increase ≥7	4/360 (1.1)	7/352 (2.0)

APPEARS THIS WAY
ON ORIGINAL

Table 95 Primary Hypercholesterolemia/Patients With Documented CHD, Diabetes Mellitus, Or CVD Risk Factors Ezetimibe Added To An Established Statin Changes From Baseline in Electrocardiograms

	Number and (Percent) of Patients	
At Last Observation	Statin+Placebo (n=390)	Statin+Ezetimibe 10 mg (n=379)
Normal at Baseline	**(n=150)**	**(n=147)**
Change, but Not Clinically Significant	28 (19)	35 (24)
No Change	111 (74)	106 (72)
Missing	11 (7)	6 (4)
Abnormal at Baseline	**(n=236)**	**(n=229)**
Clinically Significant Change	4 (2)	3 (1)
Change, but Not Clinically Significant	73 (31)	65 (28)
No Change	152 (64)	145 (63)
Missing	7 (3)	16 (7)
Change From Baseline Not Evaluable[a]	**(n=4)**	**(n=3)**

a: Subject was missing results at baseline.