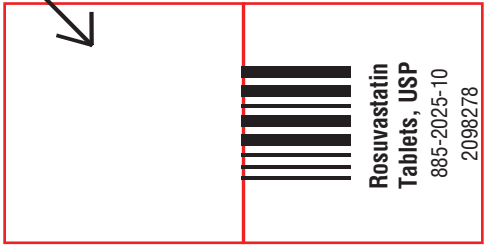


2D Data Matrix to be printed with serial number on each leaflet. The number should not be repeated

Note: Position of the pharma code and product name will change as per the folding machine feasibility



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ROSUVASTATIN TABLETS safely and effectively. See full prescribing information for ROSUVASTATIN TABLETS.

ROSUVASTATIN tablets, for oral use

Initial U.S. Approval: 2003

INDICATIONS AND USAGE

- Rosuvastatin tablets are an HMG Co-A reductase inhibitor (statin) indicated: (1)
 - To reduce the risk of major adverse cardiovascular (CV) events (CV death, nonfatal myocardial infarction, nonfatal stroke, or an arterial revascularization procedure) in adults without established coronary heart disease who are at increased risk of CV disease based on age, high-sensitivity C-reactive protein (hsCRP) ≥ 2 mg/L, and at least one additional CV risk factor.
- As an adjunct to diet to:
 - reduce LDL-C in adults with primary hyperlipidemia.
 - reduce LDL-C and slow the progression of atherosclerosis in adults.
 - reduce LDL-C in adults and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH).
- As an adjunct to other LDL-C-lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 7 years and older with homozygous familial hypercholesterolemia (HoFH).
- As an adjunct to diet for the treatment of adults with:
 - Primary dysbetalipoproteinemia.
 - Hypertriglyceridemia.

DOSEAGE AND ADMINISTRATION

Take orally with or without food, at any time of day. (2.1)
Assess LDL-C when clinically appropriate, as early as 4 weeks after initiating rosuvastatin tablets, and adjust dosage if necessary. (2.1)
Adults: Recommended dosage range is 5 to 40 mg once daily. (2.1)
Pediatric Patients with HeFH: Recommended dosage range is 5 to 10 mg once daily for patients aged 8 to less than 10 years of age, and 5 to 20 mg once daily for patients aged 10 years and older. (2.2)
Pediatric Patients with HoFH: Recommended dosage is 20 mg once daily for patients aged 7 years and older. (2.2)
Asian Patients: Initiate at 5 mg once daily. Consider risks and benefits of treatment if not adequately controlled at doses up to 20 mg once daily. (2.4)
Patients with Severe Renal Impairment (not on hemodialysis): Initiate at 5 mg once daily; do not exceed 10 mg once daily. (2.5)
See full prescribing information for rosuvastatin dosage and administration modifications due to drug interactions. (2.6)

DOSEAGE FORMS AND STRENGTHS

Tablets: 5 mg, 10 mg, 20 mg, and 40 mg of rosuvastatin. (3)

FULL PRESCRIBING INFORMATION: CONTENTS*

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Rosuvastatin tablets are indicated:

- To reduce the risk of major adverse cardiovascular (CV) events (CV death, nonfatal myocardial infarction, nonfatal stroke, or an arterial revascularization procedure) in adults without established coronary heart disease who are at increased risk of CV disease based on age, high-sensitivity C-reactive protein (hsCRP) ≥ 2 mg/L, and at least one additional CV risk factor.
- As an adjunct to diet to:
 - Reduce low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia.
 - Reduce LDL-C and slow the progression of atherosclerosis in adults.
 - Reduce LDL-C in adults and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH).
- As an adjunct to other LDL-C-lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 7 years and older with homozygous familial hypercholesterolemia (HoFH).
- As an adjunct to diet for the treatment of adults with:
 - Primary dysbetalipoproteinemia.
 - Hypertriglyceridemia.

2 DOSAGE AND ADMINISTRATION

2.1 General Dosage and Administration Information

- Administer rosuvastatin tablets orally as a single dose at any time of day, with or without food. Swallow the tablets whole.
- Assess LDL-C when clinically appropriate, as early as 4 weeks after initiating rosuvastatin tablets, and adjust the dosage if necessary.
- If a dose is missed, advise patients not to take an extra dose. Resume treatment with the next dose.
- When taking rosuvastatin tablets with an aluminum and magnesium hydroxide combination antacid, administer rosuvastatin tablets at least 2 hours before the antacid [see *Drug Interactions* (7.2)].
- 2.2 Recommended Dosage in Adult Patients**
 - The dosage range for rosuvastatin tablets is 5 to 40 mg orally once daily.
 - The recommended dose of rosuvastatin tablets depends on a patient's indication for usage, LDLC, and individual risk for CV events.
- 2.3 Recommended Dosage in Pediatric Patients**
Dosage in Pediatric Patients 8 Years of Age and Older with HeFH
The recommended dosage range is 5 mg to 10 mg orally once daily in patients aged 8 years to less than 10 years and 5 mg to 20 mg orally once daily in patients aged 10 years and older.
Dosage in Pediatric Patients 7 Years of Age and Older with HoFH
The recommended dosage is 20 mg orally once daily.

2.4 Dosing in Asian Patients

Initiate rosuvastatin tablets at 5 mg once daily due to increased rosuvastatin plasma concentrations. Consider the risks and benefits of rosuvastatin tablets when treating Asian patients not adequately controlled at doses up to 20 mg once daily [see *Warnings and Precautions* (5.1), *Use in Specific Populations* (8.8), and *Clinical Pharmacology* (12.3)].

2.5 Recommended Dosage in Patients with Renal Impairment

In patients with severe renal impairment (CL_{cr} less than 30 mL/min/1.73 m²) not on hemodialysis, the recommended starting dosage is 5 mg once daily and should not exceed 10 mg once daily [see *Warnings and Precautions* (5.1) and *Use in Specific Populations* (8.6)]. There are no dosage adjustment recommendations for patients with mild and moderate renal impairment.

2.6 Dosage Modifications Due to Drug Interactions

Table 1 displays dosage modifications for rosuvastatin tablets due to drug interactions [see *Warnings and Precautions* (5.1) and *Drug Interactions* (7.1)].

Table 1: Rosuvastatin Tablets Dosage Modifications Due to Drug Interactions

Concomitantly Used Drug	Rosuvastatin Tablets Dosage Modifications
Cyclosporine	Do not exceed 5 mg once daily.
Teriflunomide	Do not exceed 10 mg once daily.
Enasidenib	Do not exceed 10 mg once daily.
Capmatinib	Do not exceed 10 mg once daily.
Fostamatinib	Do not exceed 20 mg once daily.
Febuxostat	Do not exceed 20 mg once daily.
Gemfibrozil	Avoid concomitant use. If used concomitantly, initiate at 5 mg once daily and do not exceed 10 mg once daily.
Tafamidis	Avoid concomitant use. If used concomitantly, initiate at 5 mg once daily and do not exceed 20 mg once daily.
Antiviral Medications	
o Sofosbuvir/Velpatasvir/Voxilaprevir	Concomitant use not recommended.
o Simeprevir	Initiate at 5 mg once daily. Do not exceed 10 mg once daily.
o Dasabuvir/ombitasvir/paritaprevir/ritonavir	
o Ebasvir/Grazoprevir	
o Sofosbuvir/Velpatasvir	
o Glecaprevir/Pibrentasvir	
o Atazanavir/Ritonavir	
o Lopinavir/Ritonavir	
Darolutamide	Do not exceed 5 mg once daily.
Regorafenib	Do not exceed 10 mg once daily.

3 DOSAGE FORMS AND STRENGTHS

- 5 mg: Light yellow to yellow, round, bevel edged biconvex film coated tablets, debossed with 'H' on one side and 'R3' on the other side.
- 10 mg: Light pink to pink, round, bevel edged biconvex film coated tablets, debossed with 'H' on one side and 'R4' on the other side.
- 20 mg: Light pink to pink, round, bevel edged biconvex film coated tablets, debossed with 'H' on one side and 'R5' on the other side.
- 40 mg: Light pink to pink, oval, bevel edged biconvex film coated tablets, debossed with 'H' on one side and 'R6' on the other side.

4 CONTRAINDICATIONS

- Rosuvastatin is contraindicated in the following conditions:
 - Acute liver failure or decompensated cirrhosis [see *Warnings and Precautions* (5.3)].
 - Hypersensitivity to rosuvastatin or any excipients. Hypersensitivity reactions including rash, pruritus, urticaria, and angioedema have been reported with rosuvastatin [see *Adverse Reactions* (6.1)].

5 WARNINGS AND PRECAUTIONS

5.1 Myopathy and Rhabdomyolysis

Rosuvastatin may cause myopathy [muscle pain, tenderness, or weakness associated with elevated creatine kinase (CK)] and rhabdomyolysis. Acute kidney injury secondary to myoglobinuria and rare fatalities have occurred as a result of rhabdomyolysis with statins, including rosuvastatin.

Risk Factors for Myopathy

Risk factors for myopathy include age 65 years or greater, uncontrolled hypothyroidism, renal impairment, concomitant use with certain other drugs (including other lipid-lowering therapies), and higher rosuvastatin dosage. Asian patients on rosuvastatin may be at higher risk for myopathy [see *Drug Interactions* (7.1) and *Use in Specific Populations* (8.8)]. The myopathy risk is greater in patients taking rosuvastatin 40 mg daily compared with lower rosuvastatin dosages.

Steps to Prevent or Reduce the Risk of Myopathy and Rhabdomyolysis

The concomitant use of rosuvastatin with cyclosporine or gemfibrozil is not recommended. rosuvastatin dosage modifications are recommended for patients taking certain antiviral medications, darolutamide, and regorafenib [see *Dosage and Administration* (2.6)]. Niacin, fibrates, and colchicine may also increase the risk of myopathy and rhabdomyolysis [see *Drug Interactions* (7.1)].
Discontinue rosuvastatin if markedly elevated CK levels occur or if myopathy is either diagnosed or suspected. Muscle symptoms and CK elevations may resolve if rosuvastatin is discontinued. Temporarily discontinue rosuvastatin in patients experiencing an acute or serious condition at high risk of developing renal failure secondary to rhabdomyolysis (e.g., sepsis, shock, severe hypovolemia, major surgery, trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy).
Inform patients of the risk of myopathy and rhabdomyolysis when starting or increasing the rosuvastatin dosage. Instruct patients to promptly report any unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

5.2 Immune-Mediated Necrotizing Myopathy

There have been rare reports of immune-mediated necrotizing myopathy (IMNM), an autoimmune myopathy, associated with statin use, including reports of recurrence when the same or a different statin was administered. IMNM is characterized by proximal muscle weakness and elevated serum creatine kinase that persist despite discontinuation of statin treatment; positive anti-HMG CoA reductase antibody; muscle biopsy showing necrotizing myopathy; and improvement with immunosuppressive agents. Additional neuromuscular and serologic testing may be necessary. Treatment with immunosuppressive agents may be required. Discontinue rosuvastatin if IMNM is suspected.

5.3 Hepatic Dysfunction

Increases in serum transaminases have been reported with use of rosuvastatin [see *Adverse Reactions* (6.1)]. In most cases, these changes appeared soon after initiation, were transient, were not accompanied by symptoms, and resolved or improved on continued therapy or after a brief interruption in therapy. In a pooled analysis of placebo-controlled trials, increases in serum transaminases to more than three times the ULN occurred in 1.1% of patients taking rosuvastatin versus 0.5% of patients treated with placebo. Marked persistent increases of hepatic transaminases have also occurred with rosuvastatin. There have been rare postmarketing reports of fatal and non-fatal hepatic failure in patients taking statins, including rosuvastatin. Patients who consume substantial quantities of alcohol and/or have a history of liver disease may be at increased risk for hepatic injury [see *Use in Specific Populations* (8.7)].
Consider liver enzyme testing before rosuvastatin initiation and when clinically indicated thereafter. Rosuvastatin is contraindicated in patients with acute liver failure or decompensated cirrhosis [see *Contraindications* (4)]. If serious hepatic injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs, promptly discontinue rosuvastatin.

5.4 Proteinuria and Hematuria

In the rosuvastatin clinical trial program, dipstick-positive proteinuria and microscopic hematuria were observed among rosuvastatin treated patients. These findings were more frequent in patients taking rosuvastatin 40 mg, when compared to lower doses of rosuvastatin or comparator statins, though it was generally transient and was not associated with worsening renal function. Although the clinical significance of this finding is unknown, consider a dose reduction for patients on rosuvastatin therapy with unexplained persistent proteinuria and/or hematuria during routine urinalysis testing.

5.5 Increases in HbA1c and Fasting Serum Glucose Levels

Increases in HbA1c and fasting serum glucose levels have been reported with statins, including rosuvastatin. Based on clinical trial data with rosuvastatin, in some instances these increases may exceed the threshold for the diagnosis of diabetes mellitus [see *Adverse Reactions* (6.1)]. Optimize lifestyle measures, including regular exercise, maintaining a healthy body weight, and making healthy food choices.

5.6 Risk of Allergic Reactions Due to Tartrazine

This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

6 ADVERSE REACTIONS

The following important adverse reactions are described below and elsewhere in the labeling:

- Myopathy and Rhabdomyolysis [see *Warnings and Precautions* (5.1)]
- Immune-Mediated Necrotizing Myopathy [see *Warnings and Precautions* (5.2)]
- Hepatic Dysfunction [see *Warnings and Precautions* (5.3)]
- Proteinuria and Hematuria [see *Warnings and Precautions* (5.4)]
- Increases in HbA1c and Fasting Serum Glucose Levels [see *Warnings and Precautions* (5.5)]

CONTRAINDICATIONS

- Acute liver failure or decompensated cirrhosis. (4)
- Hypersensitivity to rosuvastatin or any excipients in rosuvastatin. (4)

WARNINGS AND PRECAUTIONS

- Myopathy and Rhabdomyolysis:** Risk factors include age 65 years or greater, uncontrolled hypothyroidism, renal impairment, concomitant use with certain other drugs, and higher rosuvastatin dosage. Asian patients may be at higher risk for myopathy. Discontinue rosuvastatin if markedly elevated CK levels occur or myopathy is diagnosed or suspected. Temporarily discontinue rosuvastatin in patients experiencing an acute or serious condition at high risk of developing renal failure secondary to rhabdomyolysis. Inform patients of the risk of myopathy and rhabdomyolysis when starting or increasing rosuvastatin dosage. Instruct patients to promptly report unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever. (5.1)
- Immune-Mediated Necrotizing Myopathy (IMNM):** Rare reports of IMNM, an autoimmune myopathy, have been reported with statin use. Discontinue rosuvastatin if IMNM is suspected. (5.2)
- Hepatic Dysfunction:** Increases in serum transaminases have occurred, some persistent. Rare reports of fatal and non-fatal hepatic failure have occurred. Consider testing liver enzymes before initiating therapy and as clinically indicated thereafter. If serious hepatic injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs, promptly discontinue rosuvastatin. (5.3)

ADVERSE REACTIONS

Most frequent adverse reactions (rate $\geq 2\%$) are headache, nausea, myalgia, asthenia, and constipation. (6.1)
To report SUSPECTED ADVERSE REACTIONS, contact Helaro Labs Limited at 1-866-495-1995 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

See full prescribing information for details regarding concomitant use of rosuvastatin with other drugs that increase the risk of myopathy and rhabdomyolysis. (7.1)
Aluminum and Magnesium Hydroxide Combination Antacids: Administer rosuvastatin at least 2 hours before the antacid. (7.2)
Warfarin: Obtain INR prior to starting rosuvastatin. Monitor INR frequently until stable upon initiation, dose titration or discontinuation. (7.3)

USE IN SPECIFIC POPULATIONS

- Pregnancy:** May cause fetal harm. (8.1)
- Lactation:** Breastfeeding not recommended during treatment with rosuvastatin. (8.2)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 10/2025

8 USE IN SPECIFIC POPULATIONS

- 8.1 Pregnancy
- 8.2 Lactation
- 8.4 Pediatric Use
- 8.5 Geriatric Use
- 8.6 Renal Impairment
- 8.7 Hepatic Impairment
- 8.8 Asian Patients

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

- 12.1 Mechanism of Action
- 12.2 Pharmacodynamics
- 12.3 Pharmacokinetics
- 12.5 Pharmacogenomics

13 NONCLINICAL TOXICOLOGY

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14 CLINICAL STUDIES

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.
Adverse reactions reported in $\geq 2\%$ of patients in placebo-controlled clinical studies and at a rate greater than placebo are shown in Table 2. These studies had a treatment duration of up to 12 weeks.

Table 2: Adverse Reactions Reported in $\geq 2\%$ of Patients Treated with Rosuvastatin and > Placebo in Placebo-Controlled Trials

Adverse Reactions	Placebo N=382	Rosuvastatin 5 mg N=291	Rosuvastatin 10 mg N=283	Rosuvastatin 20 mg N=64	Rosuvastatin 40 mg N=106	Total Rosuvastatin 5 mg to 40 mg N=744
Headache	5.0	5.5	4.9	3.1	8.5	5.5
Nausea	3.1	3.8	3.5	6.3	0	3.4
Myalgia	1.3	3.1	2.1	6.3	1.9	2.8
Asthenia	2.6	2.4	3.2	4.7	0.9	2.7
Constipation	2.4	2.1	2.1	4.7	2.8	2.4

Other adverse reactions reported in clinical studies were abdominal pain, dizziness, hypersensitivity (including rash, pruritus, urticaria, and angioedema) and pancreatitis. The following laboratory abnormalities have also been reported: dipstick-positive proteinuria and microscopic hematuria; elevated creatine phosphokinase, transaminases, glucose, glutamyl transpeptidase, alkaline phosphatase, and bilirubin; and thyroid function abnormalities.

In the METEOR study, patients were treated with rosuvastatin 40 mg (n=700) or placebo (n=281) with a mean treatment duration of 1.7 years. Adverse reactions reported in $\geq 2\%$ of patients and at a rate greater than placebo are shown in Table 3.

Table 3: Adverse Reactions Reported in $\geq 2\%$ of Patients Treated with Rosuvastatin and > Placebo in the METEOR Trial

Adverse Reactions	Placebo N=281	Rosuvastatin 40 mg N=700
Myalgia	12.1	12.7
Arthralgia	7.1	10.1
Headache	5.3	6.4
Dizziness	2.8	4.0
Increased CPK	0.7	2.6
Abdominal pain	1.8	2.4
ALT greater than 3x ULN ¹	0.7	2.2

¹ Frequency recorded as abnormal laboratory value.

In the JUPITER study, patients were treated with rosuvastatin 20 mg (n=8,901) or placebo (n=8,901) for a mean duration of 2 years. In JUPITER, there was a significantly higher frequency of diabetes mellitus reported in patients taking rosuvastatin (2.8%) versus patients taking placebo (2.3%). Mean HbA1c was significantly increased by 0.1% in rosuvastatin-treated patients compared to placebo-treated patients. The number of patients with a HbA1c $\geq 6.5\%$ at the end of the trial was significantly higher in rosuvastatin-treated versus placebo-treated patients [see *Clinical Studies* (14)].

Adverse reactions reported in $\geq 2\%$ of patients and at a rate greater than placebo are shown in Table 4.

Table 4: Adverse Reactions Reported in $\geq 2\%$ of Patients Treated with Rosuvastatin and > Placebo in the JUPITER Trial

Adverse Reactions	Placebo N=8,901	Rosuvastatin 20 mg N=8,901
Myalgia	6.6	7.6
Arthralgia	3.2	3.8
Constipation	3.0	3.3
Diabetes mellitus	2.3	2.8
Nausea	2.3	2.4

Pediatric Patients with HeFH

In a 12-week controlled study in pediatric patients 10 to 17 years of age with HeFH with rosuvastatin 5 mg to 20 mg daily [see *Use in Specific Populations* (8.4) and *Clinical Studies* (14)], elevations in serum CK greater than 10 x ULN were observed more frequently in rosuvastatin-treated patients compared with patients receiving placebo. Four of 130 (3%) patients treated with rosuvastatin (2 treated with 10 mg and 2 treated with 20 mg) had increased CK greater than 10 x ULN, compared to 0 of 46 patients on placebo.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of rosuvastatin. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Blood Disorders: thrombocytopenia

Hepatobiliary Disorders: hepatitis, jaundice, fatal and non-fatal hepatic failure

Musculoskeletal Disorders: arthralgia, rare reports of immune-mediated necrotizing myopathy associated with statin use

Nervous System Disorders: peripheral neuropathy, rare postmarketing reports of cognitive impairment (e.g., memory loss, forgetfulness, amnesia, memory impairment, and confusion) associated with the use of all statins. The reports are generally nonspecific, and reversible upon statin discontinuation, with variable times to symptom onset (1 day to years) and symptom resolution (median of 3 weeks). There have been rare reports of new-onset or exacerbation of myasthenia gravis, including ocular myasthenia, and reports of recurrence when the same or a different statin was administered.

Psychiatric Disorders: depression, sleep disorders (including insomnia and nightmares)

Reproductive System and Breast Disorders: gynecomastia

Respiratory Disorders: interstitial lung disease

Skin and Subcutaneous Tissue Disorders: drug reaction with eosinophilia and systemic symptoms (DRESS), ichthyoid drug eruption

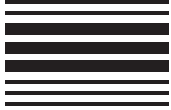
7 DRUG INTERACTIONS

7.1 Drug Interactions that Increase the Risk of Myopathy and Rhabdomyolysis with Rosuvastatin

Rosuvastatin is a substrate of CYP2C9 and transporters (such as OATP1B1, BCRP). Rosuvastatin plasma levels can be significantly increased by concomitant administration of inhibitors of CYP2C9 and transporters. Table 5 includes a list of drugs that increase the risk of myopathy and rhabdomyolysis when used concomitantly with rosuvastatin and instructions for preventing or managing them [see *Warnings and Precautions* (5.1) and *Clinical Pharmacology* (12.3)].

Table 5: Drug Interactions that Increase the Risk of Myopathy and Rhabdomyolysis with Rosuvastatin

Cyclosporine	
<i>Clinical Impact:</i>	Cyclosporine increased rosuvastatin exposure 7-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use of cyclosporine or gemfibrozil with rosuvastatin.
<i>Intervention:</i>	If used concomitantly, do not exceed a dose of rosuvastatin 5 mg once daily.
Teriflunomide	
<i>Clinical Impact:</i>	Teriflunomide increased rosuvastatin exposure more than 2.5-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.
<i>Intervention:</i>	In patients taking teriflunomide, do not exceed a dose of rosuvastatin 10 mg once daily.
Enasidenib	
<i>Clinical Impact:</i>	Enasidenib increased rosuvastatin exposure more than 2.4-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.
<i>Intervention:</i>	In patients taking enasidenib, do not exceed a dose of rosuvastatin 10 mg once daily.
Capmatinib	
<i>Clinical Impact:</i>	Capmatinib increased rosuvastatin exposure more than 2.1-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.
<i>Intervention:</i>	In patients taking capmatinib, do not exceed a dose of rosuvastatin 10 mg once daily.
Fostamatinib	
<i>Clinical Impact:</i>	Fostamatinib increased rosuvastatin exposure more than 2.0-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.
<i>Intervention:</i>	In patients taking fostamatinib, do not exceed a dose of rosuvastatin 20 mg once daily.
Febuxostat	
<i>Clinical Impact:</i>	Febuxostat increased rosuvastatin exposure more than 1.9-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.
<i>Intervention:</i>	In patients taking febuxostat, do not exceed a dose of rosuvastatin 20 mg once daily.
Gemfibrozil	
<i>Clinical Impact:</i>	Gemfibrozil significantly increased rosuvastatin exposure and gemfibrozil may cause myopathy when given alone. The risk of myopathy and rhabdomyolysis is increased with concomitant use of gemfibrozil with rosuvastatin.
<i>Intervention:</i>	Avoid concomitant use



Specific Populations

Geriatric Patients

There were no differences in plasma concentrations of rosuvastatin between the nonelderly and elderly populations (age ≥65 years).

Pediatric Patients

In a population pharmacokinetic analysis of two pediatric trials involving patients with HeFH 10 to 17 years of age and 8 to 17 years of age, respectively, rosuvastatin exposure appeared comparable to or lower than rosuvastatin exposure in adult patients.

Male and Female Patients

There were no differences in plasma concentrations of rosuvastatin between males and females.

Racial or Ethnic Groups

A population pharmacokinetic analysis revealed no clinically relevant differences in pharmacokinetics among White, Hispanic or Latino ethnicity, and Black or Afro-Caribbean groups. However, pharmacokinetic studies, including one conducted in the US, have demonstrated an approximate 2-fold elevation in median exposure (AUC and C_{max}) in Asian subjects when compared with a White control group.

Patients with Renal Impairment

Mild to moderate renal impairment (CL_{CR} ≥30 mL/min/1.73 m²) had no influence on plasma concentrations of rosuvastatin. However, plasma concentrations of rosuvastatin increased to a clinically significant extent (about 3-fold) in patients with severe renal impairment (CL_{CR} <30 mL/min/1.73 m²) not receiving hemodialysis compared with healthy subjects (CL_{CR} >80 mL/min/1.73 m²).

Steady-state plasma concentrations of rosuvastatin in patients on chronic hemodialysis were approximately 50% greater compared with healthy volunteer subjects with normal renal function.

Patients with Hepatic Impairment

In patients with chronic alcohol liver disease, plasma concentrations of rosuvastatin were modestly increased. In patients with Child-Pugh A disease, C_{max} and AUC were increased by 60% and 5%, respectively, as compared with patients with normal liver function. In patients with Child-Pugh B disease, C_{max} and AUC were increased 100% and 21%, respectively, compared with patients with normal liver function.

Drug Interaction Studies

Rosuvastatin clearance is not dependent on metabolism by cytochrome P450 3A4 to a clinically significant extent. Rosuvastatin is a substrate for certain transporter proteins including the hepatic uptake transporter organic anion-transporting polypeptide 1B1 (OATP1B1) and efflux transporter breast cancer resistance protein (BCRP). Concomitant administration of rosuvastatin with medications that are inhibitors of these transporter proteins (e.g., cyclosporine, certain HIV protease inhibitors [see *Dosage and Administration* (2.6)] and *Drug Interactions* (7.1)) and ticagrelor [see *Drug Interactions* (7.1)] may result in increased rosuvastatin plasma concentrations.

Table 8: Effect of Coadministered Drugs on Rosuvastatin Systemic Exposure

Coadministered drug and dosing regimen	Rosuvastatin		
	Dose (mg) ¹	Change in AUC	Change in C_{max}
		Mean Ratio (ratio with/without coadministered drug) No Effect=1.0	
Sofosbuvir/velpatasvir/voxilaprevir (400 mg/100 mg/100 mg) + Voxilaprevir (100 mg) once daily for 15 days	10 mg, single dose	7.39 ² (6.68 to 8.18) ²	18.88 ² (16.23 to 21.96) ²
Cyclosporine – stable dose required (75 mg to 200 mg BID)	10 mg, QD for 10 days	7.1 ²	11 ²
Darolutamide 600 mg BID, 5 days	5 mg, single dose	5.2 ²	~5 ²
Regorafenib 160 mg QD, 14 days	5 mg, single dose	3.8 ²	4.6 ²
Atazanavir/ritonavir combination 300 mg/100 mg QD for 8 days	10 mg	3.1 ²	7 ²
Simeprevir 150 mg QD, 7 days	10 mg, single dose	2.8 ² (2.3 to 3.4) ²	3.2 ² (2.6 to 3.9) ²
Velpatasvir 100 mg once daily	10 mg, single dose	2.69 ² (2.46 to 2.94) ²	2.61 ² (2.32 to 2.92) ²
Ombitasvir 25 mg/paritaprevir 150 mg/ ritonavir 100 mg + dasabuvir 400 mg BID	5 mg, single dose	2.59 ² (2.09 to 3.21) ²	7.13 ² (5.11 to 9.96) ²
Teriflumidone	Not available	2.51 ²	2.65 ²
Enasidenib 100 mg QD, 28 days	10 mg, single dose	2.44	3.66
Elbasvir 50 mg/grazoprevir 200 mg once daily	10 mg, single dose	2.26 ² (1.89 to 2.69) ²	5.49 ² (4.29 to 7.04) ²
Glecaprevir 400 mg/pibrentasvir 120 mg once daily	5 mg, once daily	2.15 ² (1.88 to 2.46) ²	5.62 ² (4.80 to 6.59) ²
Loganavir/ritonavir combination 400 mg/100 mg BID for 17 days	20 mg, QD for 7 days	2.1 ² (1.7 to 2.6) ²	5 ² (3.4 to 6.4) ²
Capmatinib 400 mg BID	10 mg, single dose	2.08 ² (1.56 to 2.76) ²	3.04 ² (2.36 to 3.92) ²
Fostatinib 100 mg BID	20 mg, single dose	1.96 ² (1.77 to 2.15) ²	1.88 ² (1.69 to 2.09) ²
Febraxostat 120 mg QD for 4 days	10 mg, single dose	1.9 ² (1.5 to 2.2) ²	2.1 ² (1.8 to 2.6) ²
Gentibrozil 600 mg BID for 7 days	80 mg	1.9 ² (1.6 to 2.2) ²	2.2 ² (1.8 to 2.7) ²
600 mg BID on Days 1 & 2, followed by QD on Days 3 to 9	10 mg	1.97 ² (1.68 to 2.31) ²	1.86 ² (1.59 to 2.16) ²
Eltrombopag 75 mg QD, 5 days	10 mg	1.6 ² (1.4 to 1.7) ²	2 ² (1.8 to 2.3) ²
Darunavir 600 mg/ritonavir 100 mg BID, 7 days	10 mg, QD for 7 days	1.5 ² (1.0 to 2.1) ²	2.4 ² (1.6 to 3.6) ²
Tipranavir/ritonavir combination 500 mg/200 mg BID for 11 days	10 mg	1.4 ² (1.2 to 1.6) ²	2.2 ² (1.8 to 2.7) ²
Dronedarine 400 mg BID	10 mg	1.4	
Itraconazole 200 mg QD, 5 days	10 mg or 80 mg	1.4 (1.2 to 1.6) ² 1.3 (1.1 to 1.4) ²	1.4 (1.2 to 1.5) ² 1.2 (0.9 to 1.4) ²
Ezetimibe 10 mg QD, 14 days	10 mg, QD for 14 days	1.2 (0.9 to 1.6) ²	1.2 (0.8 to 1.6) ²
Fosamprenavir/ritonavir 700 mg/100 mg BID for 7 days	10 mg	1.1	1.5
Fenofibrate 67 mg TID for 7 days	10 mg	↔	1.2 (1.1 to 1.3) ²
Rifampicin 450 mg QD, 7 days	20 mg	↔	
Aluminum & magnesium hydroxide combination antacid Administered simultaneously Administered 2 hours apart	40 mg 40 mg	0.5 ² (0.4 to 0.5) ² 0.8 (0.7 to 0.9) ²	0.5 ² (0.4 to 0.6) ² 0.8 (0.7 to 1.0) ²
Ketoconazole 200 mg BID for 7 days	80 mg	1.0 (0.8 to 1.2) ²	1.0 (0.7 to 1.3) ²
Fluconazole 200 mg QD for 11 days	80 mg	1.1 (1.0 to 1.3) ²	1.1 (0.9 to 1.4) ²
Erythromycin 500 mg QID for 7 days	80 mg	0.8 (0.7 to 0.9) ²	0.7 (0.5 to 0.9) ²

QD= Once daily, BID= Twice daily, TID= Three times daily, QID= Four times daily

¹ Single dose unless otherwise noted.

² Clinically significant [see *Dosage and Administration* (2) and *Warnings and Precautions* (5)]

³ Mean ratio with 90% CI (with/without coadministered drug, e.g., 1= no change, 0.7 = 30% decrease, 1.1–1.1-fold increase in exposure)

Table 9: Effect of Rosuvastatin Coadministration on Systemic Exposure to Other Drugs

Rosuvastatin Dosage Regimen	Coadministered Drug		
	Name and Dose	Change in AUC	Change in C_{max}
		Mean Ratio (ratio with/without coadministered drug) No Effect=1.0	
		Change in AUC	Change in C_{max}
		Change in AUC	Change in C_{max}
40 mg QD for 10 days	Warfarin ¹ 25 mg single dose	R-Warfarin 1.0 (1.0 to 1.1) ² S-Warfarin 1.1 (1.0 to 1.1) ²	R-Warfarin 1.0 (0.9 to 1.0) ² S-Warfarin 1.0 (0.9 to 1.1) ²
40 mg QD for 12 days	Digoxin 0.5 mg single dose	1.0 (0.9 to 1.2) ²	1.0 (0.9 to 1.2) ²
40 mg QD for 28 days	Oral Contraceptive (ethinyl estradiol 0.035 mg & norgestrel 0.180, 0.215 and 0.250 mg) QD for 21 days	EE 1.3 (1.2 to 1.3) ² NG 1.3 (1.3 to 1.4) ²	EE 1.3 (1.2 to 1.3) ² NG 1.2 (1.1 to 1.3) ²

EE = ethinyl estradiol, NG = norgestrel, QD= Once daily

¹ Clinically significant pharmacodynamic effects [see *Drug Interactions* (7.3)]

² Mean ratio with 90% CI (with/without coadministered drug, e.g., 1= no change, 0.7–30% decrease, 1.1–1.1-fold increase in exposure)

12.5 Pharmacogenomics

Disposition of rosuvastatin, involves OATP1B1 and other transporter proteins. Higher plasma concentrations of rosuvastatin have been reported in very small groups of patients (n=3 to 5) who have two reduced function alleles of the gene that encodes OATP1B1 (*SLCO1B1* 521T > C). The frequency of this genotype (i.e., *SLCO1B1* 521T > C) is generally lower than 5% in most racial/ethnic groups. The impact of this polymorphism on efficacy and/or safety of rosuvastatin has not been clearly established.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 104-week carcinogenicity study in mice given 0, 2, 20, 60, or 80 mg/kg/day by oral gavage, the incidence of uterine stromal polyps was significantly increased in females at 80 mg/kg/day at systemic exposure 20 times the human exposure at 40 mg/day based on AUC. Increased incidence of polyps was not seen at lower doses.

In a 107-week carcinogenicity study in mice given 10, 80, or 200 mg/kg/day by oral gavage, an increased incidence of hepatocellular adenoma/carcinoma was observed at 200 mg/kg/day at systemic exposures 20 times the human exposure at 40 mg/day based on AUC. An increased incidence of hepatocellular tumors was not seen at lower doses.

Rosuvastatin was not mutagenic or clastogenic with or without metabolic activation in the Ames test with *Salmonella typhimurium* and *Escherichia coli*, the mouse lymphoma assay, and the chromosomal aberration assay in Chinese hamster lung cells. Rosuvastatin was negative in the *in vivo* mouse micronucleus test.

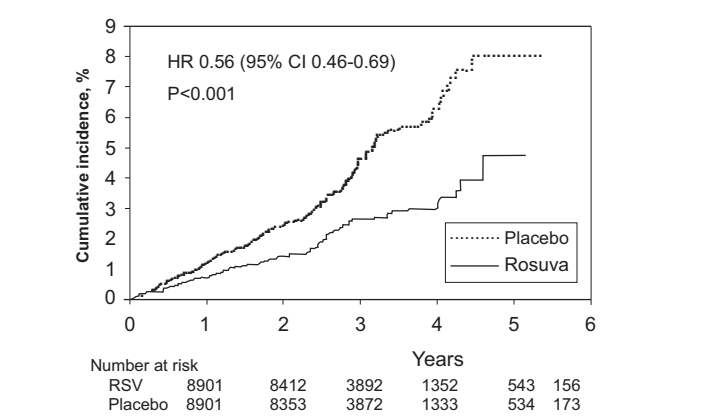
In rat fertility studies with oral gavage doses of 5, 15, 50 mg/kg/day, males were treated for 9 weeks prior to and throughout mating and females were treated 2 weeks prior to mating and throughout mating until gestation day 7. No adverse effect on fertility was observed at 50 mg/kg/day (systemic exposures up to 10 times the human exposure at 40 mg/kg/day based on AUC). In testicles of dogs treated with rosuvastatin at 30 mg/kg/day for one month, spermatid giant cells were seen. Spermatid giant cells were observed in monkeys after 6-month treatment at 30 mg/kg/day in addition to vacuolation of seminiferous tubular epithelium. Exposures in the dog were 20 times and in the monkey 10 times the human exposure at 40 mg/day based on body surface area. Similar findings have been seen with other drugs in this class.

14 CLINICAL STUDIES

Primary Prevention of CV Disease

In the Justification for the Use of Statins in Primary Prevention: An Intervention Trial Evaluating Rosuvastatin (JUPITER) study, the effect of rosuvastatin on the occurrence of major CV disease events was assessed in 17,802 males (≥50 years) and females (≥60 years) who had no clinically evident CV disease, LDL-C levels <130 mg/dL and hsCRP levels ≥2 mg/L. The study population had an estimated baseline coronary heart disease risk of 11.6% over 10 years based on the Framingham risk criteria and included a high percentage of patients with additional risk factors such as hypertension (58%), low HDL-C levels (23%), cigarette smoking (16%), or a family history of premature CHD (12%). Patients had a median baseline LDL-C of 108 mg/dL and hsCRP of 4.3 mg/L. Patients were randomly assigned to placebo (n=8901) or rosuvastatin 20 mg once daily (n=8901) and were followed for a mean duration of 2 years. The JUPITER study was stopped early by the Data Safety Monitoring Board due to meeting predefined stopping rules for efficacy in rosuvastatin-treated subjects. The primary end point was a composite event consisting of the time-to-first occurrence of any of the following major CV events: CV death, nonfatal myocardial infarction, nonfatal stroke, hospitalization for unstable angina or an arterial revascularization procedure. Rosuvastatin significantly reduced the risk of major CV events (252 events in the placebo group vs. 142 events in the rosuvastatin group) with a statistically significant (p<0.001) relative risk reduction of 44% and absolute risk reduction of 1.2% (see Figure 1). The risk reduction for the primary end point was consistent across the following predefined subgroups: age, sex, race, smoking status, family history of premature CHD, body mass index, LDL-C, HDL-C, and hsCRP levels.

Figure 1. Time to First Occurrence of Major CV Events in JUPITER

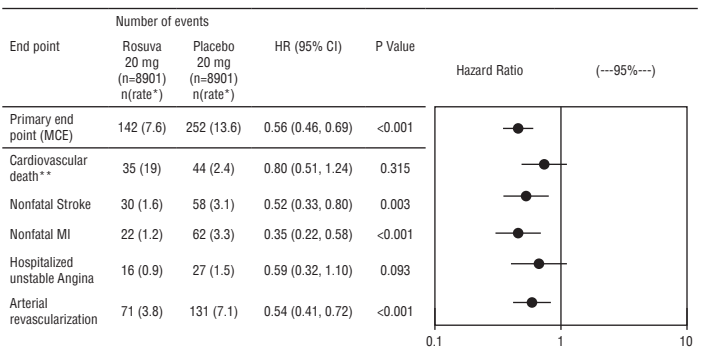


The individual components of the primary end point are presented in Figure 3. Rosuvastatin significantly reduced the risk of nonfatal myocardial infarction, nonfatal stroke, and arterial revascularization procedures. There were no significant treatment differences between the rosuvastatin and placebo groups for death due to CV causes or hospitalizations for unstable angina.

Rosuvastatin significantly reduced the risk of myocardial infarction (6 fatal events and 62 nonfatal events in placebo-treated subjects vs. 9 fatal events and 22 nonfatal events in rosuvastatin-treated subjects) and the risk of stroke (6 fatal events and 58 nonfatal events in placebo-treated subjects vs. 3 fatal events and 30 nonfatal events in rosuvastatin-treated subjects).

In a post-hoc subgroup analysis of JUPITER subjects (rosuvastatin=725, placebo=680) with hsCRP ≥2 mg/L and no other traditional risk factors (smoking, BP ≥140/90 or taking antihypertensives, low HDL-C) other than age, after adjustment for high HDL-C, there was no significant treatment benefit with rosuvastatin treatment.

Figure 2. Major CV Events by Treatment Group in JUPITER



¹ event rate/1000-patient-years

² * Cardiovascular death included fatal MI, fatal stroke, sudden death, and other adjudicated causes of CV death

At one year, rosuvastatin increased HDL-C and reduced LDL-C, hsCRP, total cholesterol and serum triglyceride levels (p<0.001 for all versus placebo).

Primary Hyperlipidemia in Adults

Rosuvastatin reduces Total-C, LDL-C, ApoB, non-HDL-C, and TG, and increases HDL-C, in adult patients with hyperlipidemia and mixed dyslipidemia.

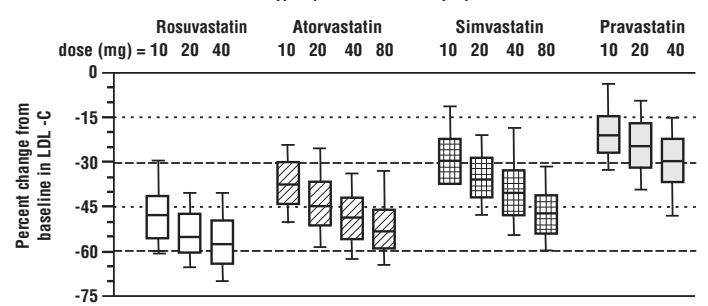
In a multicenter, double-blind, placebo-controlled study in patients with hyperlipidemia, rosuvastatin given as a single daily dose (5 to 40 mg) for 6 weeks significantly reduced Total-C, LDL-C, non-HDL-C, and ApoB, across the dose range (Table 10).

Table 10: Lipid-Modifying Effect of Rosuvastatin in Adult Patients with Hyperlipidemia (Adjusted Mean % Change from Baseline at Week 6)

Dose	N	Total-C	LDL-C	Non-HDL-C	ApoB	TG	HDL-C
Placebo	13	-5	-7	-7	-3	-3	3
Rosuvastatin 5 mg	17	-33	-45	-44	-38	-35	13
Rosuvastatin 10 mg	17	-36	-52	-48	-42	-10	14
Rosuvastatin 20 mg	17	-40	-55	-51	-46	-23	8
Rosuvastatin 40 mg	18	-46	-63	-60	-54	-28	10

Rosuvastatin was compared with the statins (atorvastatin, simvastatin, and pravastatin) in a multicenter, open-label, dose-ranging study of 2,240 patients with hyperlipidemia or mixed dyslipidemia. After randomization, patients were treated for 6 weeks with a single daily dose of either rosuvastatin, atorvastatin, simvastatin, or pravastatin (see Figure 3 and Table 11).

Figure 3. Percent LDL-C Change by Dose of Rosuvastatin, Atorvastatin, Simvastatin, and Pravastatin at Week 6 in Adult Patients with Hyperlipidemia or Mixed Dyslipidemia



Box plots are a representation of the 25th, 50th, and 75th percentile values, with whiskers representing the 10th and 90th percentile values. Mean baseline LDL-C: 189 mg/dL

Table 11: Percent Change in LDL-C by Dose of Rosuvastatin, Atorvastatin, Simvastatin, and Pravastatin From Baseline to Week 6 (LS Mean)¹ in Adult Patients with Hyperlipidemia or Mixed Dyslipidemia (Sample Sizes Ranging from 156 to 167 Patients Per Group)

Treatment	Treatment Daily Dose			
	10 mg	20 mg	40 mg	80 mg
Rosuvastatin	-46 ²	-52 ²	-55 ²	–
Atorvastatin	-37	-43	-48	-51
Simvastatin	-28	-35	-39	-46
Pravastatin	-20	-24	-30	–

¹ Corresponding standard errors are approximately 1.00.

² Rosuvastatin 10 mg reduced LDL-C significantly more than atorvastatin 10 mg; pravastatin 10 mg, 20 mg, and 40 mg; simvastatin 10 mg, 20 mg, and 40 mg (p<0.002)

³ Rosuvastatin 20 mg reduced LDL-C significantly more than atorvastatin 20 mg and 40 mg; pravastatin 20 mg and 40 mg; simvastatin 20 mg, 40 mg, and 80 mg (p<0.002)

⁴ Rosuvastatin 40 mg reduced LDL-C significantly more than atorvastatin 40 mg; pravastatin 40 mg; simvastatin 40 mg, and 80 mg (p<0.002)

Slowing of the Progression of Atherosclerosis

In the *Measuring Effects on Intima Media Thickness: an Evaluation Of Rosuvastatin 40 mg (METEOR)* study, the effect of therapy with rosuvastatin on carotid atherosclerosis was assessed by B-mode ultrasonography in patients with elevated LDL-C, at low risk (Framingham risk <10% over ten years) for symptomatic coronary artery disease and with subclinical atherosclerosis as evidenced by carotid intima-media thickness (cIMT). In this double-blind, placebo-controlled clinical study 984 adult patients were randomized (of whom 876 were analyzed) in a 5:2 ratio to rosuvastatin 40 mg or placebo once daily. Ultrasonograms of the carotid walls were used to determine the annualized rate of change per patient from baseline to two years in mean maximum cIMT of 12 measured segments. The estimated difference in the rate of change in the maximum cIMT analyzed over all 12 carotid artery sites between patients treated with rosuvastatin and placebo-treated patients was -0.0145 mm/year (95% CI -0.0196, -0.0093; p=0.0001).

The annualized rate of change from baseline for the placebo group was +0.0131 mm/year (p<0.0001). The annualized rate of change from baseline for the group treated with rosuvastatin was -0.0014 mm/year (p=0.32).

At an individual patient level in the group treated with rosuvastatin 52.1% of patients demonstrated an absence of disease progression (defined as a negative annualized rate of change), compared to 37.7% of patients in the placebo group.

HeFH in Adults

In a study of adult patients with HeFH (baseline mean LDL of 291 mg/dL), patients were randomized to rosuvastatin 20 mg or atorvastatin 20 mg. The dose was increased at 6-week intervals. Significant LDL-C reductions from baseline were seen at each dose in both treatment groups (see Table 12).

Table 12: LDL-C Percent Change from Baseline

	Week	Dose (mg)	Rosuvastatin (n=435) LS Mean ¹ (95% CI)		Atorvastatin (n=187) LS Mean ¹ (95% CI)	
			Week 6	Week 12	Week 18	Week 18
	20	40	-47% (-49%, -46%)	-55% (-57%, -54%)	-38% (-40%, -36%)	-52% (-54%, -50%)

¹ LS Means are least square means adjusted for baseline LDL-C

HeFH in Pediatric Patients

In a double-blind, randomized, multicenter, placebo-controlled, 12-week study, 176 (97 male and 79 female) pediatric patients with HeFH were randomized to rosuvastatin 5 mg, 10 mg or 20 mg or placebo daily. Patients ranged in age from 10 to 17 years (median age of 14 years) with approximately 30% of the patients 10 to 13 years and approximately 17%, 18%, 40%, and 25% of Tanner stages II, III, IV, and V, respectively. Females were at least 1-year postmenstruation. Mean LDL-C at baseline was 233 mg/dL (range of 129 to 399). The 12-week double-blind phase was followed by a 40-week open-label dose-titration phase, during which all patients (n=173) received 5 mg, 10 mg or 20 mg rosuvastatin daily.

Rosuvastatin significantly reduced LDL-C (primary end point), total cholesterol and ApoB levels at each dose compared to placebo. Results are shown in Table 13 below.

Table 13: Lipid-Modifying Effects of Rosuvastatin in Pediatric Patients 10 to 17 years of Age with HeFH (Least-Squares Mean Percent Change from Baseline to Week 12)

Dose (mg)	N	LDL-C	HDL-C	Total-C	TG ¹	ApoB
Placebo	46	-1%	+7%	0%	-7%	-2%
5	42	-38%	+4% ²	-30%	-13% ²	-32%
10	44	-45%	+11% ²	-34%	-15% ²	-38%
20	44	-50%	+9% ²	-39%	-16% ²	-41%

¹ Median percent change

² Difference from placebo not statistically significant

Rosuvastatin was also studied in a two-year open-label, uncontrolled, titration-to-goal trial that included 175 pediatric patients with HeFH who were 8 to 17 years old (79 males and 96 females). All patients had a documented genetic defect in the LDL receptor or in ApoB. Approximately 89% were White, 7% were Asian, 1% were Black or African American, and fewer than 1% were Hispanic or Latino ethnicity. Mean LDL-C at baseline was 236 mg/dL. Fifty-eight (33%) patients were prepubertal at baseline. The starting rosuvastatin dosage for all pediatric patients was 5 mg once daily. Pediatric patients aged 8 to less than 10 years (n=41 at baseline) could titrate to a maximum dosage of 10 mg once daily, and pediatric patients aged 10 to 17 years could titrate to a maximum dosage of 20 mg once daily.

The reductions in LDL-C from baseline were generally consistent across age groups within the trial as well as with previous experience in both adult and pediatric controlled trials.

HeFH in Adult and Pediatric Patients

In an open-label, forced-titration study, HoFH patients (n=40, 8 to 63 years) were evaluated for their response to rosuvastatin 20 to 40 mg titrated at a 6-week interval. In the overall population, the mean LDL-C reduction from baseline was 22%. About one-third of the patients benefited from increasing their dose from 20 mg to 40 mg with further LDL-C lowering of greater than 6%. In the 27 patients with at least a 15% reduction in LDL-C, the mean LDL-C reduction was 30% (median 28% reduction). Among 13 patients with an LDL-C reduction of <15%, 3 had no change or an increase in LDL-C. Reductions in LDL-C of 15% or greater were observed in 5 of 5 patients with known receptor negative status.

HeFH in Pediatric Patients

Rosuvast