ROSUVASTATIN CALCIUM- rosuvastatin calcium tablet
Umedica Laboratories USA Inc.

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

RECENT MAJOR CHANGES

Indications and Usage (1) 04/2026
Dosage and Administration, Dosage Modifications Due to Drug Interactions (2.6) 09/2026

INDICATIONS AND USAGE

Rosuvastatin tablet is 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 at increased risk for these events.
- As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C):
  - in adults with primary hypercholesterolemia.
  - and slow the progression of atherosclerosis in adults.
  - in adults and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH).
  - 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.

DOSAGE 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. (2.2)
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. (2.3)
Pediatric Patients with HoFH: Recommended dosage is 20 mg once daily for patients aged 7 years and older. (2.3)
Asian Patients: Initiate at 5 mg once daily. Consider risks and benefits of treatment if not adequately controlled at dosages 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 tablet dosage and administration modifications due to drug interactions. (2.6)

DOSAGE FORMS AND STRENGTHS

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

CONTRAINDICATIONS

Acute liver failure or decompensated cirrhosis. (4)
Hypersensitivity to rosuvastatin or any excipients in rosuvastatin tablets. (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 tablets dosage. Asian patients may be at higher risk for myopathy. Discontinue rosuvastatin tablets if markedly elevated CK levels occur or myopathy is diagnosed or suspected. Temporarily discontinue rosuvastatin tablets 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 tablets 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 tablets 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 tablets. (5.3)

ADVERSE REACTIONS

Most frequent adverse reactions (rate ≥2%) are headache, nausea, myalgia, asthenia, and constipation. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Umedica Laboratories USA Inc. at 1-855-288-5777 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 tablets with other drugs that increase the risk of myopathy and rhabdomyolysis. (7.1)
*Aluminum and Magnesium Hydroxide Combination Antacids:*Administer rosuvastatin tablets at least 2 hours before the antacid. (7.2)
*Warfarin:*Obtain INR prior to starting rosuvastatin tablets. 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 tablets. (8.2)

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

Revised: 10/2026

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Rosuvastatin tablets is 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 at increased risk for these events.
- As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C):
  - in adults with hypercholesterolemia.
  - and slow the progression of atherosclerosis in adults.
  - in adults and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH).
  - 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 dosage of rosuvastatin tablets depends on a patient’s indication for usage, LDL-C, 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 Recommended Dosage 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 dosages 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 m^2) 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**
Sofosbuvir/velpatasvir/voxilaprevir or Ledipasvir/sofosbuvir	Avoid concomitant use.
Gemfibrozil	Avoid concomitant use. If use is unavoidable, initiate at 5 mg once daily and do not exceed 10 mg once daily.
Tafamidis	Avoid concomitant use. If use is unavoidable, initiate at 5 mg once daily and do not exceed 20 mg once daily.
Belumosudil	Do not exceed 5 mg once daily.
Cyclosporine	Do not exceed 5 mg once daily.
Darolutamide	Do not exceed 5 mg once daily.
Vadadustat	Do not exceed 5 mg

Vadadustat	once daily.
Additional Antiviral Medications	
◦ Simeprevir ◦ Dasabuvir/ombitasvir/paritaprevir/ritonavir ◦ Elbasvir/Grazoprevir ◦ Sofosbuvir/Velpatasvir ◦ Glecaprevir/Pibrentasvir ◦ Atazanavir/Ritonavir ◦ Lopinavir/Ritonavir	Initiate at 5 mg once daily. Do not exceed 10 mg once daily.
Capmatinib	Do not exceed 10 mg once daily.
Enasidenib	Do not exceed 10 mg once daily.
Momelotinib	Do not exceed 10 mg once daily.
Regorafenib	Do not exceed 10 mg once daily.
Teriflunomide	Do not exceed 10 mg once daily.
Ticagrelor	Do not exceed 20 mg once daily. In patients at increased risk for rhabdomyolysis, consider dosages less than 20 mg per day.
Febuxostat	Do not exceed 20 mg once daily.
Fostamatinib	Do not exceed 20 mg once daily.

3 DOSAGE FORMS AND STRENGTHS

- 5 mg of rosuvastatin: Pink, round, biconvex, beveled edge, film coated tablets debossed with “R5” on one side and plain on other side.
- 10 mg of rosuvastatin: Pink, round, biconvex, beveled edge, film coated tablets debossed with “R10” on one side and plain on other side.
- 20 mg of rosuvastatin: Pink, round, biconvex, film coated tablets debossed with “R20” on one side and plain on other side.
- 40 mg of rosuvastatin: Pink, oval, biconvex, film-coated tablets debossed with “R40” on one side and plain on other side.

4 CONTRAINDICATIONS

Rosuvastatin tablets is contraindicated in patients with:

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

5 WARNINGS AND PRECAUTIONS

5.1 Myopathy and Rhabdomyolysis

Rosuvastatin tablets 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 tablets.

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 tablets dosage. Asian patients on rosuvastatin tablets 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 tablets 40 mg daily compared with lower rosuvastatin tablets dosages.

Steps to Prevent or Reduce the Risk of Myopathy and Rhabdomyolysis
Rosuvastatin tablets dosage modifications are recommended for patients taking certain medications; concomitant use with certain other medications should be avoided *[see Dosage and Administration (2.6), Drug Interactions (7.1)].*

Discontinue rosuvastatin tablets if markedly elevated CK levels occur or if myopathy is either diagnosed or suspected. Muscle symptoms and CK elevations may resolve if rosuvastatin tablets is discontinued. Temporarily discontinue rosuvastatin tablets 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 tablets 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 tablets if IMNM is suspected.

5.3 Hepatic Dysfunction

Increases in serum transaminases have been reported with use of rosuvastatin tablets *[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 tablets versus 0.5% of patients treated with placebo. Marked persistent increases of hepatic transaminases have also occurred with rosuvastatin tablets. There have been rare postmarketing reports of fatal and non-fatal hepatic failure in patients taking statins, including rosuvastatin tablets.

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)]*

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Consider liver enzyme testing before rosuvastatin tablets initiation and when clinically indicated thereafter. Rosuvastatin tablets 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 tablets.

5.4 Proteinuria and Hematuria

In the Rosuvastatin tablets clinical trial program, dipstick-positive proteinuria and microscopic hematuria were observed among rosuvastatin tablets treated patients. These findings were more frequent in patients taking rosuvastatin tablets 40 mg, when compared to lower doses of rosuvastatin tablets 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 tablets 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 tablets. Based on clinical trial data with rosuvastatin tablets, 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.

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)]*

6.1 Clinical Trials Experience

Because clinical trails 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 trails of another drug and may not reflect the rates observed in clinical practice.

Adverse reactions reported in ≥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 ≥2% of Patients Treated with Rosuvastatin Tablets 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-40 mg N=744

	%	%	%	%	%	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 tablets 40 mg (n=700) or placebo (n=281) with a mean treatment duration of 1.7 years. Adverse reactions reported in ≥2% of patients and at a rate greater than placebo are shown in Table 3.

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

Adverse Reactions	**Placebo N=281 %**	**Rosuvastatin tablets 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 tablets 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 tablets (2.8%) versus patients taking placebo (2.3%). Mean HbA1c was significantly increased by 0.1% in rosuvastatin tablets-treated patients compared to placebo-treated patients. The number of patients with a HbA1c >6.5% at the end of the trial was significantly higher in rosuvastatin tablets-treated versus placebo-treated patients *[see Clinical Studies (14)]*.

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

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

Adverse Reactions	**Placebo N=8,901 %**	**Rosuvastatin Tablets 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 tablets 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 tablets treated patients compared with patients receiving placebo. Four of 130 (3%) patients treated with rosuvastatin tablets (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 tablets. 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 nonserious, 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), lichenoid drug eruption

7 DRUG INTERACTIONS

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

Rosuvastatin is a substrate of CYP2C9 and transporters (such as OATP1B1, BCRP). Rosuvastatin plasma levels can be significantly increased with 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 tablets 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 Tablets

Sofosbuvir/velpatasvir/voxilaprevir or Ledipasvir/sofosbuvir	
Prevention or	Avoid concomitant use with rosuvastatin tablets

Management:	Avoid concomitant use with rosuvastatin tablets.
Mechanism and Clinical Effect(s):	Rosuvastatin plasma levels were significantly increased with concomitant administration of many anti-viral drugs, which increases the risk of myopathy and rhabdomyolysis.
Gemfibrozil	
Prevention or Management:	Avoid concomitant use of gemfibrozil with rosuvastatin tablets. If use is unavoidable, initiate rosuvastatin tablets at 5 mg once daily and do not exceed a dosage of rosuvastatin tablets 10 mg once daily .
Mechanism and Clinical Effect(s):	Gemfibrozil significantly increased rosuvastatin exposure and gemfibrozil may cause myopathy when given alone. The risk of myopathy and rhabdomyolysis is increased with concomitant use.
Tafamidis	
Prevention or Management:	Avoid concomitant use of tafamidis with rosuvastatin tablets. If use is unavoidable, initiate rosuvastatin tablets at 5 mg once daily and do not exceed a dosage of rosuvastatin tablets 20 mg once daily. Monitor for signs of myopathy and rhabdomyolysis if used concomitantly with rosuvastatin tablets .
Mechanism and Clinical Effect(s):	Tafamidis significantly increased rosuvastatin exposure and tafamidis may cause myopathy when given alone. The risk of myopathy and rhabdomyolysis is increased with concomitant use.
Belumosudil	
Prevention or Management:	In patients taking belumosudil, do not exceed a dosage of rosuvastatin tablets 5 mg once daily .
Mechanism and Clinical Effect(s):	Belumosudil increased rosuvastatin exposure more than 4.6-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.
Cyclosporine	
Prevention or Management:	In patients taking cyclosporine, do not exceed a dosage of rosuvastatin tablets 5 mg once daily.
Mechanism and Clinical Effect(s):	Cyclosporine increased rosuvastatin exposure 7-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.
Darolutamide	
Prevention or Management:	In patients taking darolutamide, do not exceed a dosage of rosuvastatin tablets 5 mg once daily .
Mechanism and Clinical Effect(s):	Darolutamide increased rosuvastatin exposure more than 5-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.
Vadadustat	
Prevention or Management:	In patients taking vadadustat, do not exceed a dosage of rosuvastatin tablets 5 mg once daily.
Mechanism and Clinical Effect(s):	Vadadustat increased rosuvastatin exposure by 2.5-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.

Additional Anti-Viral Medications		
Prevention or Management:	• Simeprevir • Dasabuvir/ombitasvir/paritaprevir/ritonavir • Elbasvir/grazoprevir • Sofosbuvir/velpatasvir • Glecaprevir/pibrentasvir • Atazanavir/ritonavir • Lopinavir/ritonavir	Initiate with rosuvastatin tablets 5 mg once daily, and do not exceed a dosage of rosuvastatin tablets 10 mg once daily.
Mechanism and Clinical Effect(s):	Rosuvastatin plasma levels were significantly increased with concomitant administration of many anti-viral drugs, which increases the risk of myopathy and rhabdomyolysis.	
Capmatinib		
Prevention or Management:	In patients taking capmatinib, do not exceed a dosage of rosuvastatin tablets 10 mg once daily .	
Mechanism and Clinical Effect(s):	Capmatinib increased rosuvastatin exposure more than 2.1-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.	
Enasidenib		
Prevention or Management:	In patients taking enasidenib, do not exceed a dosage of rosuvastatin tablets 10 mg once daily .	
Mechanism and Clinical Effect(s):	Enasidenib increased rosuvastatin exposure more than 3.4-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.	
Momelotinib		
Prevention or Management:	In patients taking momelotinib, do not exceed a dosage of rosuvastatin tablets 10 mg once daily.	
Mechanism and Clinical Effect(s):	Momelotinib increased rosuvastatin exposure by 2.7-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.	
Regorafenib		
Prevention or Management:	In patients taking regorafenib, do not exceed a dosage of rosuvastatin tablets 10 mg once daily .	
Mechanism and Clinical Effect(s):	Regorafenib increased rosuvastatin exposure and may increase the risk of myopathy and rhabdomyolysis.	
Teriflunomide		
Prevention or Management:	In patients taking teriflunomide, do not exceed a dosage of rosuvastatin tablets 10 mg once daily .	
Mechanism and Clinical Effect(s):	Teriflunomide increased rosuvastatin exposure more than 2.5-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.	
Ticagrelor		
	In patients taking ticagrelor, do not exceed a dosage of	

Prevention or Management:	rosuvastatin tablets 20 mg once daily. In patients at increased risk for rhabdomyolysis *[see Warnings and Precautions (5.1)]* , consider dosages less than 20 mg per day.
Mechanism and Clinical Effect(s):	Ticagrelor increased rosuvastatin exposure by 2.3-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.
Febuxostat	
Prevention or Management:	In patients taking febuxostat, do not exceed a dosage of rosuvastatin tablets 20 mg once daily .
Mechanism and Clinical Effect(s):	Febuxostat increased rosuvastatin exposure more than 1.9-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.
Fostamatinib	
Prevention or Management:	In patients taking fostamatinib, do not exceed a dosage of rosuvastatin tablets 20 mg once daily .
Mechanism and Clinical Effect(s):	Fostamatinib increased rosuvastatin exposure more than 2.0-fold. The risk of myopathy and rhabdomyolysis is increased with concomitant use.
Fenofibrates (e.g., fenofibrate and fenofibric acid)	
Prevention or Management:	Consider if the benefit of using fibrates concomitantly with rosuvastatin tablets outweighs the increased risk of myopathy and rhabdomyolysis. If concomitant use is decided, monitor patients for signs and symptoms of myopathy, particularly during initiation of therapy and during upward dosage titration of either drug.
Mechanism and Clinical Effect(s):	Fibrates may cause myopathy when given alone. The risk of myopathy and rhabdomyolysis is increased with concomitant use.
Colchicine	
Prevention or Management:	Consider if the benefit of using colchicine concomitantly with rosuvastatin tablets outweighs the increased risk of myopathy and rhabdomyolysis. If concomitant use is decided, monitor patients for signs and symptoms of myopathy, particularly during initiation of therapy and during upward dosage titration of either drug.
Mechanism and Clinical Effect(s):	Cases of myopathy and rhabdomyolysis have been reported with concomitant use of colchicine with rosuvastatin tablets.
Niacin	
Prevention or Management:	Consider if the benefit of using lipid-modifying dosages (≥1 g/day) of niacin concomitantly with rosuvastatin tablets outweighs the increased risk of myopathy and rhabdomyolysis. If concomitant use is decided, monitor patients for signs and symptoms of myopathy, particularly during initiation of therapy and during upward dosage titration of either drug.
Mechanism	Cases of myopathy and rhabdomyolysis have occurred

and Clinical Effect(s):	with concomitant use of lipid-modifying dosages (≥1 g/day) of niacin with rosuvastatin tablets.

7.2 Drug Interactions that Decrease the Efficacy of Rosuvastatin Tablets

Table 6 presents drug interactions that may decrease the efficacy of rosuvastatin tablets and instructions for preventing or managing them.

Table 6: Drug Interactions that Decrease the Efficacy of Rosuvastatin Tablets

Antacids	
Prevention or Management:	In patients taking antacid, administer rosuvastatin tablets at least 2 hours before the antacid .
Mechanism and Clinical Effect(s):	Concomitant aluminum and magnesium hydroxide combination antacid administration decreased the mean exposure of rosuvastatin 50% *[see Clinical Pharmacology (12.3)].*

7.3 Rosuvastatin Tablets Effects on Other Drugs

Table 7 presents rosuvastatin tablets's effect on other drugs and instructions for preventing or managing them.

Table 7: Rosuvastatin Tablets Effects on Other Drugs

Warfarin	
Prevention or Management:	In patients taking warfarin, obtain an INR before starting rosuvastatin tablets and frequently enough after initiation, dose titration or discontinuation to ensure that no significant alteration in INR occurs. Once the INR is stable, monitor INR at regularly recommended intervals.
Mechanism and Clinical Effect(s):	Rosuvastatin significantly increased the INR in patients receiving warfarin *[see Clinical Pharmacology (12.3)].*

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Discontinue rosuvastatin tablets when pregnancy is recognized. Alternatively, consider the ongoing therapeutic needs of the individual patient.

Rosuvastatin tablets decreases synthesis of cholesterol and possibly other biologically active substances derived from cholesterol; therefore, rosuvastatin tablets may cause fetal harm when administered to pregnant patients based on the mechanism of action *[see Clinical Pharmacology (12.1)*]. In addition, treatment of hypercholesterolemia is not generally necessary during pregnancy. Atherosclerosis is a chronic process and the discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia for most patients.

Available data from case series and prospective and retrospective observational cohort studies over decades of use with statins in pregnant women have not identified a drug-

associated risk of major congenital malformations. Published data from prospective and retrospective observational cohort studies with rosuvastatin tablets use in pregnant women are insufficient to determine if there is a drug-associated risk of miscarriage *(see Data)*.

In animal reproduction studies, no adverse developmental effects were observed in pregnant rats or rabbits orally administered rosuvastatin during the period of organogenesis at doses that resulted in systemic exposures equivalent to human exposures at the maximum recommended human dose (MRHD) of 40 mg/day, based on AUC and body surface area (mg/m ^{2}), respectively *(see Data)*.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Human Data

A Medicaid cohort linkage study of 1,152 statin-exposed pregnant women compared to 886,996 controls did not find a significant teratogenic effect from maternal use of statins in the first trimester of pregnancy, after adjusting for potential confounders – including maternal age, diabetes mellitus, hypertension, obesity, and alcohol and tobacco use – using propensity score-based methods. The relative risk of congenital malformations between the group with statin use and the group with no statin use in the first trimester was 1.07 (95% confidence interval 0.85 to 1.37) after controlling for confounders, particularly pre-existing diabetes mellitus. There were also no statistically significant increases in any of the organ-specific malformations assessed after accounting for confounders. In the majority of pregnancies, statin treatment was initiated prior to pregnancy and was discontinued at some point in the first trimester when pregnancy was identified. Study limitations include reliance on physician coding to define the presence of a malformation, lack of control for certain confounders such as body mass index, use of prescription dispensing as verification for the use of a statin, and lack of information on non-live births.

Animal Data

In female rats given 5, 15 and 50 mg/kg/day before mating and continuing through to gestation day 7 resulted in decreased fetal body weight (female pups) and delayed ossification at 50 mg/kg/day (10 times the human exposure at the MRHD of 40 mg/day based on AUC).

In pregnant rats given 2, 10 and 50 mg/kg/day of rosuvastatin from gestation day 7 through lactation day 21 (weaning), decreased pup survival occurred at 50 mg/kg/day (dose equivalent to 12 times the MRHD of 40 mg/day based body surface area).

In pregnant rabbits given 0.3, 1, and 3 mg/kg/day of rosuvastatin from gestation day 6 to day 18, decreased fetal viability and maternal mortality was observed at 3 mg/kg/day (dose equivalent to the MRHD of 40 mg/day based on body surface area).

Rosuvastatin crosses the placenta in rats and rabbits and is found in fetal tissue and amniotic fluid at 3% and 20%, respectively, of the maternal plasma concentration following a single 25 mg/kg oral gavage dose on gestation day 16 in rats. In rabbits, fetal tissue distribution was 25% of maternal plasma concentration after a single oral gavage dose of 1 mg/kg on gestation day 18.

8.2 Lactation

Risk Summary

Limited data from case reports in published literature indicate that rosuvastatin is present in human milk. There is no available information on the effects of the drug on

the breastfed infant or the effects of the drug on milk production. Statins, including rosuvastatin, decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol and may cause harm to the breastfed infant.

Because of the potential for serious adverse reactions in a breastfed infant, based on the mechanism of action, advise patients that breastfeeding is not recommended during treatment with rosuvastatin tablets *[see Use in Specific Populations (8.1)and Clinical Pharmacology (12.1)]* .

8.4 Pediatric Use

The safety and effectiveness of rosuvastatin tablets as an adjunct to diet to reduce LDL-C have been established in pediatric patients 8 years of age and older with HeFH. Use of rosuvastatin tablets for this indication is based on one 12-week controlled trial with a 40-week open-label extension period in 176 pediatric patients 10 years of age and older with HeFH and one 2-year open-label, uncontrolled trial in 175 pediatric patients 8 years of age and older with HeFH *[see Clinical Studies (14)]*. In the 1-year trial with a 12-week controlled phase, there was no detectable effect of rosuvastatin tablets on growth, weight, BMI (body mass index), or sexual maturation in patients aged 10 to 17 years.

The safety and effectiveness of rosuvastatin tablets as an adjunct to other LDL-C-lowering therapies to reduce LDL-C have been established in pediatric patients 7 years of age and older with HoFH. Use of rosuvastatin tablets for this indication is based on a randomized, placebo-controlled, cross-over study in 14 pediatric patients 7 years of age and older with HoFH *[see Clinical Studies (14)]*.

The safety and effectiveness of rosuvastatin tablets have not been established in pediatric patients younger than 8 years of age with HeFH, younger than 7 years of age with HoFH, or in pediatric patients with other types of hypercholesterolemia (other than HeFH or HoFH).

8.5 Geriatric Use

Of the 10,275 patients in clinical studies with rosuvastatin tablets, 3,159 (31%) were 65 years and older, and 698 (6.8%) were 75 years and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects.

Advanced age (≥65 years) is a risk factor for rosuvastatin tablets-associated myopathy and rhabdomyolysis. Dose selection for an elderly patient should be cautious, recognizing the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy and the higher risk of myopathy. Monitor geriatric patients receiving rosuvastatin tablets for the increased risk of myopathy *[see Warnings and Precautions (5.1)]*.

8.6 Renal Impairment

Rosuvastatin exposure is not influenced by mild to moderate renal impairment (CL_{cr} ≥30 mL/min/1.73 m^2). Exposure to rosuvastatin is increased to a clinically significant extent in patients with severe renal impairment (CL_{cr} <30 mL/min/1.73 m^2) who are not receiving hemodialysis *[see Clinical Pharmacology (12.3)]* .

Renal impairment is a risk factor for myopathy and rhabdomyolysis. Monitor all patients with renal impairment for development of myopathy. In patients with severe renal impairment not on hemodialysis, the recommended starting dosage is 5 mg daily and should not exceed 10 mg daily *[see Dosage and Administration (2.5) and Warnings and Precautions (5.1)]* .

8.7 Hepatic Impairment

Rosuvastatin is contraindicated in patients with acute liver failure or decompensated cirrhosis. Chronic alcohol liver disease is known to increase rosuvastatin exposure. Patients who consume substantial quantities of alcohol and/or have a history of liver disease may be at increased risk for hepatic injury *[see Contraindications (4), Warnings and Precautions (5.3) and Clinical Pharmacology (12.3)]* .

8.8 Asian Patients

Pharmacokinetic studies have demonstrated an approximate 2-fold increase in median exposure to rosuvastatin in Asian subjects when compared with White controls. Adjust the rosuvastatin tablets dosage in Asian patients *[see Dosage and Administration (2.4) and Clinical Pharmacology (12.3)]* .

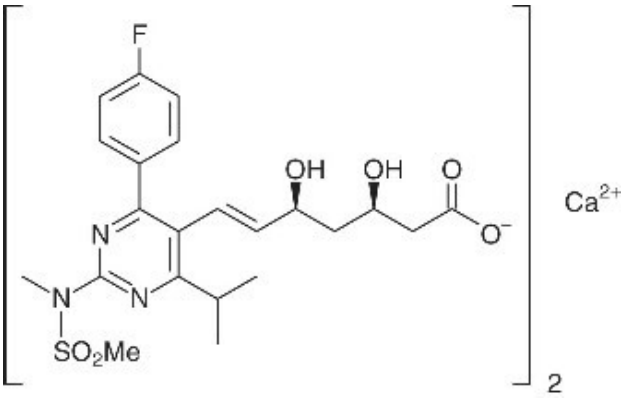
10 OVERDOSAGE

No specific antidotes for rosuvastatin tablets are known. Hemodialysis does not significantly enhance clearance of rosuvastatin. In the event of overdose, consider contacting the Poison Help line (1800-222-1222) or a medical toxicologist for additional overdosage management recommendations.

11 DESCRIPTION

Rosuvastatin calcium USP is a 3-hydroxy-3-methylglutaryl coenzyme A (HMG CoA)-reductase inhibitor.

The chemical name for rosuvastatin calcium USP is 6-Heptenoic acid, 7-[4-(4-fluorophenyl)-6-(1-methylethyl)-2-[methyl(methylsulfonyl) amino]-5-pyrimidinyl]-3,5-dihydroxy-, calcium salt (2:1), (3R,5S,6E) with the following structural formula:



The empirical formula for rosuvastatin calcium USP is $(C_{22}H_{27}FN_3O_6S)_2Ca$ and the molecular weight is 1,001.14. Rosuvastatin calcium USP is a White or almost white, hygroscopic powder that is freely soluble in methylene chloride, slightly soluble in water practically insoluble in anhydrous ethanol. Rosuvastatin calcium is a hydrophilic compound with a partition coefficient (octanol/water) of 0.13 at pH of 7.0.

Rosuvastatin tablets for oral use contain rosuvastatin 5 mg, 10 mg, 20 mg, or 40 mg (equivalent to 5.2 mg, 10.4 mg, 20.8 mg, and 41.6 mg rosuvastatin calcium) and the following inactive ingredients: crospovidone USP, hypromellose USP, iron oxide red NF, lactose monohydrate USP, magnesium stearate USP, microcrystalline cellulose USP, sodium bicarbonate powder NF, titanium dioxide USP, triacetin USP.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Rosuvastatin tablets is an inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A to mevalonate, a precursor of cholesterol.

12.2 Pharmacodynamics

Inhibition of HMG-CoA reductase by rosuvastatin accelerates the expression of LDL-receptors, followed by the uptake of LDL-C from blood to the liver, leading to a decrease in plasma LDL-C and total cholesterol. Sustained inhibition of cholesterol synthesis in the liver also decreases levels of very-low-density lipoproteins. The maximum LDL-C reduction of rosuvastatin tablets is usually achieved by 4 weeks and is maintained after that.

12.3 Pharmacokinetics

Absorption
In clinical pharmacology studies in man, peak plasma concentrations of rosuvastatin were reached 3 to 5 hours following oral dosing. Both C_{max} and AUC increased in approximate proportion to rosuvastatin tablets dose. The absolute bioavailability of rosuvastatin is approximately 20%. The AUC of rosuvastatin does not differ following evening or morning drug administration.

Effect of food
Administration of rosuvastatin tablets with food did not affect the AUC of rosuvastatin.

Distribution
Mean volume of distribution at steady-state of rosuvastatin is approximately 134 liters. Rosuvastatin is 88% bound to plasma proteins, mostly albumin. This binding is reversible and independent of plasma concentrations.

Elimination
Metabolism
Rosuvastatin is not extensively metabolized; approximately 10% of a radiolabeled dose is recovered as metabolite. The major metabolite is N-desmethyl rosuvastatin, which is formed principally by cytochrome P450 / 2C9, and *in vitro*studies have demonstrated that N-desmethyl rosuvastatin has approximately one-sixth to one-half the HMG-CoA reductase inhibitory activity of the parent compound. Overall, greater than 90% of active plasma HMG-CoA reductase inhibitory activity is accounted for by the parent compound.

Excretion
Following oral administration, rosuvastatin and its metabolites are primarily excreted in the feces (90%). After an intravenous dose, approximately 28% of total body clearance was via the renal route, and 72% by the hepatic route. The elimination half-life of rosuvastatin is approximately 19 hours.

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 m^2) 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 m^2) not receiving hemodialysis compared with healthy subjects (CL_{cr} >80 mL/min/1.73 m^2).

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 polyprotein 1B1 (OATP1B1) and efflux transporter breast cancer resistance protein (BCRP). Concomitant administration of rosuvastatin tablets 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**		
		Mean Ratio (ratio with/without coadministered drug) No Effect=1.0	
	Dose (mg) *1*	**Change in AUC**	**Change in C_{max}**
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) *3*	18.88 *2* (16.23 to 21.96) *3*
Cyclosporine – stable dose required (75 mg – 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]
Belumosudil 200 mg QD, 8 days	10 mg, single dose on 2 separate days	4.62 [2]	3.59 [2]
Regorafenib 160 mg QD, 14 days	5 mg, single dose	3.8 [2]	4.6 [2]
Enasidenib 100 mg QD, 28 days	10 mg, single dose	3.4 [2]	4.66 [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) [3]	3.2 [2] (2.6 to 3.9) [3]
Momelotinib 200 mg OD, 5 days	10 mg, single dose	2.7 [2]	3.2 [2]
Velpatasvir 100 mg once daily	10 mg, single dose	2.69 [2] (2.46 to 2.94) [3]	2.61 [2] (2.32 to 2.92) [3]
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) [3]	7.13 [2] (5.11 to 9.96) [3]
Teriflunomide	Not available	2.51 [2]	2.65 [2]
Ticagrelor 90 mg BID	10 mg, single dose 20 mg, single dose	2.3 [2] 2.3 [2]	2.4 [2] 2.6 [2]
Vadadustat 600 mg OD, 8 days	20 mg, single dose on 2 separate days	2.47 [2]	2.75 [2]
Elbasvir 50 mg/grazoprevir 200 mg once daily	10 mg, single dose	2.26 [2] (1.89 to 2.69) [3]	5.49 [2] (4.29 to 7.04) [3]
Glecaprevir 400 mg/pibrentasvir 120 mg once daily	5 mg, once daily	2.15 [2] (1.88 to 2.46) [3]	5.62 [2] (4.80 to 6.59) [3]
Lopinavir/ritonavir combination 400 mg/100 mg BID for 17 days	20 mg, QD for 7 days	2.1 [2] (1.7 to 2.6) [3]	5 [2] (3.4 to 6.4) [3]
Capmatinib 400 mg BID	10 mg, single dose	2.08 [2] (1.56 to 2.76) [3]	3.04 [2] (2.36 to 3.92) [3]
Fostamatinib 100 mg BID	20 mg, single dose	1.96 [2] (1.77 to 2.15) [3]	1.88 [2] (1.69 to 2.09) [3]
Febuxostat 120 mg QD for 4 days	10 mg, single dose	1.9 [2] (1.5 to 2.5) [3]	2.1 [2] (1.8 to 2.6) [3]
Gemfibrozil 600 mg BID for 7 days	80 mg	1.9 [2] (1.6 to 2.2) [3]	2.2 [2] (1.8 to 2.7) [3]

Tafamidis 61 mg BID on Days 1 & 2, followed by QD on Days 3 to 9	10 mg	1.97 [2] (1.68 to 2.31) [3]	1.86 [2] (1.59 to 2.16) [3]
Eltrombopag 75 mg QD, 5 days	10 mg	1.6 (1.4 to 1.7) [3]	2 (1.8 to 2.3) [3]
Darunavir 600 mg/ritonavir 100 mg BID, 7 days	10 mg, QD for 7 days	1.5 (1.0 to 2.1) [3]	2.4 (1.6 to 3.6) [3]
Tipranavir/ritonavir combination 500 mg/200 mg BID for 11 days	10 mg	1.4 (1.2 to 1.6) [3]	2.2 (1.8 to 2.7) [3]
Dronedarone 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) [3] 1.3 (1.1 to 1.4) [3]	1.4 (1.2 to 1.5) [3] 1.2 (0.9 to 1.4) [3]
Ezetimibe 10 mg QD, 14 days	10 mg, QD for 14 days	1.2 (0.9 to 1.6) [3]	1.2 (0.8-1.6) [3]
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) [3]
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) [3] 0.8 (0.7 to 0.9) [3]	0.5 [2] (0.4 to 0.6) [3] 0.8 (0.7 to 1.0) [3]
Ketoconazole 200 mg BID for 7 days	80 mg	1.0 (0.8 to 1.2) [3]	1.0 (0.7 to 1.3) [3]
Fluconazole 200 mg QD for 11 days	80 mg	1.1 (1.0 to 1.3) [3]	1.1 (0.9 to 1.4) [3]
Erythromycin 500 mg QID for 7 days	80 mg	0.8 (0.7 to 0.9) [3]	0.7 (0.5 to 0.9) [3]

QD/OD= 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, 11=11-fold increase in exposure)

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

Rosuvastatin Dosage Regimen	Coadministered Drug		
		Mean Ratio (ratio with/without coadministered drug) No Effect = 1.0	
	Name and Dose	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,11=11-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*521 C/C) is generally lower than 5% in most racial/ethnic groups. The impact of this polymorphism on efficacy and/or safety of rosuvastatin tablets has not been clearly established.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

In a 104-week carcinogenicity study in rats at dose levels of 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, 60, 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.

Mutagenesis

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.

Impairment of Fertility

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/day based on AUC). In testicles of dogs treated with rosuvastatin at 30 mg/kg/day for one month, spermatidic giant cells were seen. Spermatidic 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

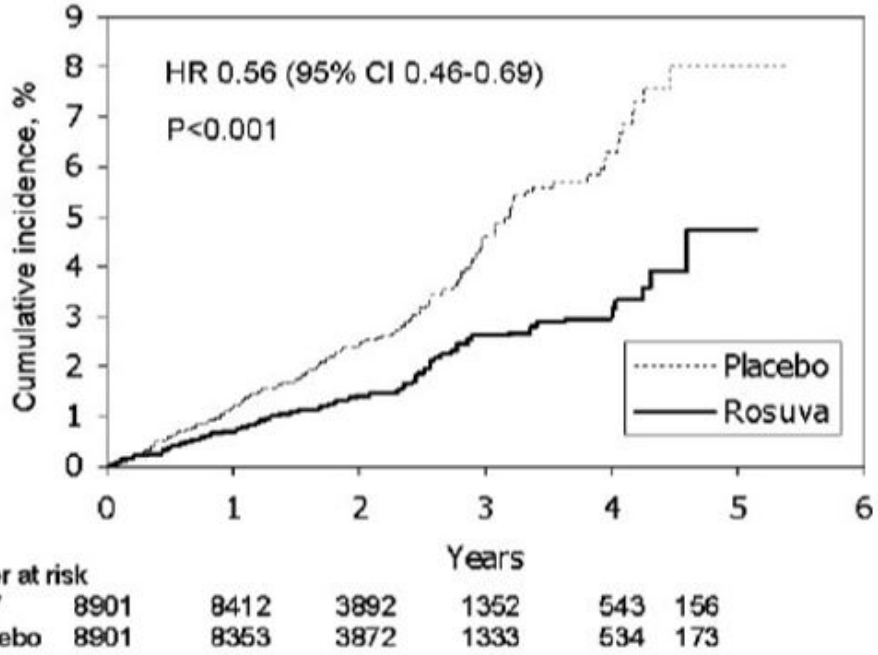
Primary Prevention of CV Disease

In the Justification for the Use of Statins in Primary Prevention: An Intervention Trial Evaluating Rosuvastatin (JUPITER) study, the effect of rosuvastatin tablets 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=8,901) or rosuvastatin tablets 20 mg once daily (n=8,901) 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 tablets-treated subjects.

The primary end point was a composite end point 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 tablets 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



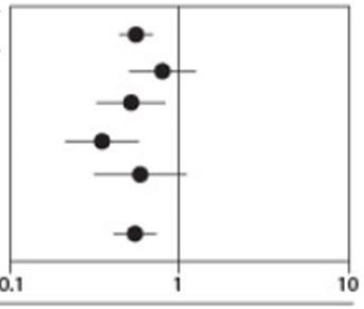
The individual components of the primary end point are presented in Figure 2. Rosuvastatin tablets significantly reduced the risk of nonfatal myocardial infarction, nonfatal stroke, and arterial revascularization procedures. There were no significant treatment differences between the rosuvastatin tablets and placebo groups for death due to CV causes or hospitalizations for unstable angina.

Rosuvastatin tablets 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 tablets-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 tablets-treated subjects).

In a post-hoc subgroup analysis of JUPITER subjects (rosuvastatin=725, placebo=680) with a 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 tablets treatment.

Figure 2. Major CV Events by Treatment Group in JUPITER

End point	Number of events: Rosuva 20 mg (n=8901) n (rate*)	Number of events: Placebo 20 mg (n=8901) n (rate*)	HR (95% CI)	P value
Primary end point (MCE)	142 (7.6)	252 (13.6)	0.56 (0.46, 0.69)	<0.001
Cardiovascular death**	35 (1.9)	44 (2.4)	0.80 (0.51, 1.24)	0.315
Nonfatal Stroke	30 (1.6)	58 (3.1)	0.52 (0.33, 0.80)	0.003
Nonfatal MI	22 (1.2)	62 (3.3)	0.35 (0.22, 0.58)	<0.001
Hospitalized unstable Angina	16 (0.9)	27 (1.5)	0.59 (0.32, 1.10)	0.093
Arterial revascularization	71 (3.8)	131 (7.1)	0.54 (0.41, 0.72)	<0.001



* event rate/1000-patient years
** Cardiovascular death included fatal MI, fatal stroke, sudden death, and other adjudicated causes of CV death

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

Primary Hypercholesterolemia in Adults

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

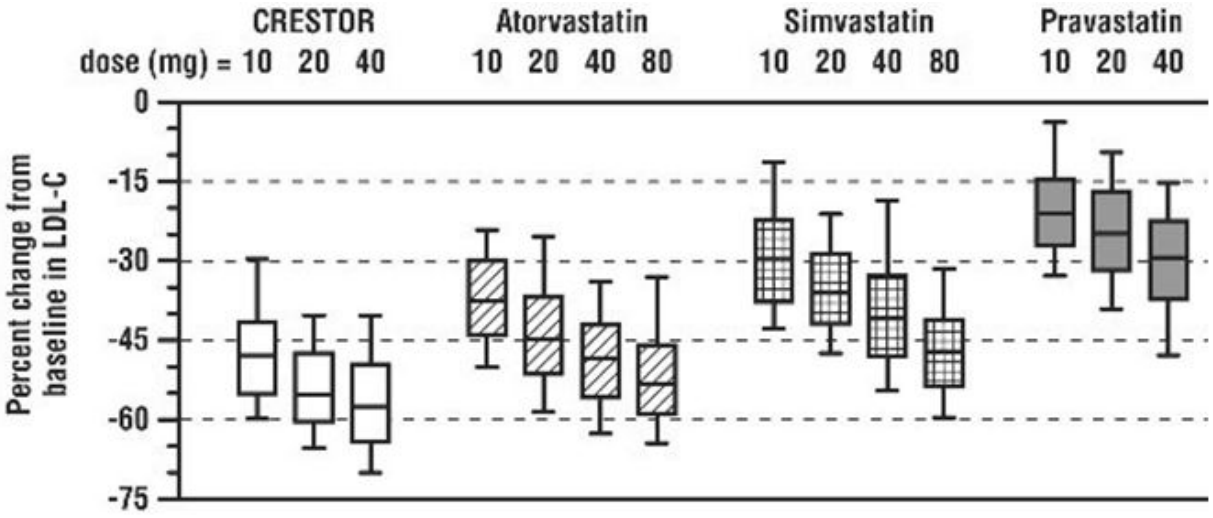
In a multicenter, double-blind, placebo-controlled study in patients with hypercholesterolemia, rosuvastatin tablets given as a single daily dose (5 to 40 mg) for 6 weeks significantly reduced Total-C, LDL-C, non-HDL-C, and ApoB, across the dose range (Table 10).

Table 10: Lipid-modifying Effect of Rosuvastatin Tablets in Adult Patients with Hypercholesterolemia (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 tablets 5 mg	17	-33	-45	-44	-38	-35	13
Rosuvastatin tablets 10 mg	17	-36	-52	-48	-42	-10	14
Rosuvastatin tablets 20 mg	17	-40	-55	-51	-46	-23	8
Rosuvastatin tablets 40 mg	18	-46	-63	-60	-54	-28	10

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

Figure 3. Percent LDL-C Change by Dose of Rosuvastatin Tablets, Atorvastatin, Simvastatin, and Pravastatin at Week 6 in Adult Patients with hypercholesterolemia 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 Tablets, Atorvastatin, Simvastatin, and Pravastatin From Baseline to Week 6 (LS Mean [1]) in Adult Patients with Hypercholesterolemia or Mixed Dyslipidemia

(Sample Sizes Ranging from 156–167 Patients Per Group)

	Treatment Daily Dose			
Treatment	**10 mg**	**20 mg**	**40 mg**	**80 mg**
Rosuvastatin	-46 [2]	-52 [3]	-55 [4]	---
Atorvastatin	-37	-43	-48	-51
Simvastatin	-28	-35	-39	-46
Pravastatin	-20	-24	-30	---

[1] Corresponding standard errors are approximately 1.00.
[2] Rosuvastatin tablets 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 tablets 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 tablets 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 tablets 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 intimal-medial 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 tablets 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 tablets 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 tablets was -0.0014 mm/year ($p=0.32$).

At an individual patient level in the group treated with rosuvastatin tablets, 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 tablets 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 (Table 12).

Table 12: LDL-C Percent Change from Baseline

		Rosuvastatin tablets (n=435) LS Mean [1] (95% CI)	**Atorvastatin (n=187) LS Mean[1](95% CI)**
Week 6	20 mg	-47% (-49%, -46%)	-38% (-40%, -36%)
Week 12	40 mg	-55% (-57%, -54%)	-47% (-49%, -45%)

Week 18	80 mg	NA	-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% at Tanner stages II, III, IV, and V, respectively. Females were at least 1 year postmenarche. 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, where 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 Tablets 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.

HoFH 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 tablets 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 3 of 5 patients with known receptor negative status.

HoFH in Pediatric Patients

Rosuvastatin tablets was studied in a randomized, double-blind, placebo-controlled, multicenter, cross-over study in 14 pediatric patients with HoFH. The study included a 4-week dietary lead-in phase during which patients received rosuvastatin tablets 10 mg daily, a cross-over phase that included two 6-week treatment periods with either rosuvastatin tablets 20 mg or placebo in random order, followed by a 12-week open-label phase during which all patients received rosuvastatin tablets 20 mg. Patients ranged in age from 7 to 15 years of age (median 11 years), 50% were male, 71% were White, 21% were Asian, 7% were Black or African American, and no patients were of Hispanic or Latino ethnicity. Fifty percent were on apheresis therapy and 57% were taking ezetimibe. Patients who entered the study on apheresis therapy or ezetimibe continued the treatment throughout the entire study. Mean LDL-C at baseline was 416 mg/dL (range 152 to 716 mg/dL). A total of 13 patients completed both treatment periods of the randomized cross-over phase; one patient withdrew consent due to inability to have blood drawn during the cross-over phase.

Rosuvastatin tablets 20 mg significantly reduced LDL-C, total cholesterol, ApoB, and non-HDL-C compared to placebo (see Table 14).

Table 14: Lipid-modifying Effects of Rosuvastatin Tablets in Pediatric Patients 7 to 15 years of Age with HoFH After 6 Weeks

	Placebo (N=13)	**Rosuvastatin tablets 20 mg (N=13)**	**Percent difference (95% CI)**
LDL-C (mg/dL)	481	396	-22.3% (-33.5, -9.1) [1]
Total-C (mg/dL)	539	448	-20.1% (-29.7, -9.1) [2]
Non-HDL-C (mg/dL)	505	412	-22.9% (-33.7, -10.3) [2]
ApoB (mg/dL)	268	235	-17.1% (-29.2, -2.9) [3]
% Difference estimates are based on transformations of the estimated mean difference in log LDL measurements between rosuvastatin tablets and placebo using a mixed model adjusted for study period [1] p=0.005, [2] p=0.003, [3] p=0.024			

Primary Dysbetalipoproteinemia in Adults

In a randomized, multicenter, double-blind cross-over study, 32 adult patients [27 with ϵ2/ϵ2 and 4 with apo E mutation (Arg145Cys)] with primary dysbetalipoproteinemia entered a 6-week dietary lead-in period on the NCEP Therapeutic Lifestyle Change (TLC) diet. Following dietary lead-in, patients were randomized to a sequence of treatments for 6 weeks each: rosuvastatin 10 mg followed by rosuvastatin 20 mg or rosuvastatin 20 mg followed by rosuvastatin 10 mg. Rosuvastatin tablets reduced non HDL-C (primary end point) and circulating remnant lipoprotein levels. Results are shown in the Table 15, below.

Table 15: Lipid-Modifying Effects of Rosuvastatin Tablets 10 mg and 20 mg in Adult Patients with Primary Dysbetalipoproteinemia (Type III hyperlipoproteinemia) After Six Weeks by Median Percent Change (95% CI) from Baseline (N=32)

		Median percent	**Median percent**

	Median at Baseline (mg/dL)	change from baseline (95% CI) Rosuvastatin tablets 10 mg	change from baseline (95% CI) Rosuvastatin tablets 20 mg
Total-C	342.5	-43.3 (-46.9, - 37.5)	-47.6 (-51.6, -42.8)
Triglycerides	503.5	-40.1 (-44.9, -33.6)	-43.0 (-52.5, -33.1)
Non-HDL-C	294.5	-48.2 (-56.7, -45.6)	-56.4 (-61.4, -48.5)
VLDL-C + IDL-C	209.5	-46.8 (-53.7, -39.4)	-56.2 (-67.7, -43.7)
LDL-C	112.5	-54.4 (-59.1, -47.3)	-57.3 (-59.4, -52.1)
HDL-C	35.5	10.2 (1.9, 12.3)	11.2 (8.3, 20.5)
RLP-C	82.0	-56.4 (-67.1, -49.0)	-64.9 (-74.0, -56.6)
Apo-E	16.0	-42.9 (-46.3, -33.3)	-42.5 (-47.1, -35.6)

Hypertriglyceridemia in Adults
In a double-blind, placebo-controlled study in adult patients with baseline TG levels from 273 to 817 mg/dL, rosuvastatin tablets given as a single daily dose (5 to 40 mg) over 6 weeks significantly reduced serum TG levels (see Table 16).

Table 16: Lipid-Modifying Effect of Rosuvastatin Tablets in Adult Patients with Primary Hypertriglyceridemia After Six Weeks by Median (Min, Max) Percent Change from Baseline to Week 6

Dose	Placebo (n=26)	Rosuvastatin tablets 5 mg (n=25)	Rosuvastatin tablets 10 mg (n=23)	Rosuvastatin tablets 20 mg (n=27)	Rosuvastatin tablets 40 mg (n=25)
Triglycerides	1 (-40, 72)	-21 (-58, 38)	-37 (-65, 5)	-37 (-72, 11)	-43 (-80, -7)
Non-HDL-C	2 (-13, 19)	-29 (-43, -8)	-49 (-59, -20)	-43 (-74, 12)	-51 (-62, -6)
Total-C	1 (-13, 17)	-24 (-40, -4)	-40 (-51, -14)	-34 (-61, -11)	-40 (-51, -4)
LDL-C	5 (-30, 52)	-28 (-71, 2)	-45 (-59, 7)	-31 (-66, 34)	-43 (-61, -3)
HDL-C	-3 (-25, 18)	3 (-38, 33)	8 (-8, 24)	22 (-5, 50)	17 (-14, 63)

16 HOW SUPPLIED/STORAGE AND HANDLING

Rosuvastatin Tablets USP are supplied as follows:

Strength	How Supplied	NDC	Tablet Description

5 mg	Bottle of 30 tablets	NDC 60290-043-01	Pink, round, biconvex, beveled edge, film coated tablets debossed with “R5” on one side and plain on other side.
	Bottle of 90 tablets	NDC 60290-043-02	
	Bottle of 500 tablets	NDC 60290-043-03	
	Blister pack of 100 unit-dose tablets	NDC 60290-043-04	
	Bottle of 1000 tablets	NDC 60290-043-05	
10 mg	Bottle of 30 tablets	NDC 60290-044-01	Pink, round, biconvex, beveled edge, film coated tablets debossed with “R10” on one side and plain on other side.
	Bottle of 90 tablets	NDC 60290-044-02	
	Bottle of 500 tablets	NDC 60290-044-03	
	Blister pack of 100 unit-dose tablets	NDC 60290-044-04	
	Bottle of 1000 tablets	NDC 60290-044-05	
20 mg	Bottle of 30 tablets	NDC 60290-045-01	Pink, round, biconvex, film coated tablets debossed with “R20” on one side and plain on other side.
	Bottle of 90 tablets	NDC 60290-045-02	
	Bottle of 500 tablets	NDC 60290-045-03	
	Blister pack of 100 unit-dose tablets	NDC 60290-045-04	
	Bottle of 1000 tablets	NDC 60290-045-05	
40 mg	Bottle of 30 tablets	NDC 60290-046-01	Pink, oval, biconvex, film-coated tablets debossed with “R40” on one side and
	Bottle of 90 tablets	NDC 60290-046-02	
	Bottle of 500 tablets	NDC 60290-	

	500 tablets	046-03	plain on other side.
	Blister pack of 100 unit-dose tablets	NDC 60290-046-04	
	Bottle of 1000 tablets	NDC 60290-046-05	

Storage

Store at controlled room temperature, 20°C to 25ºC (68°F to 77ºF); excursions permitted between 15ºC and 30ºC (59°F and 86ºF) [see USP Controlled Room Temperature]. Protect from moisture.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Myopathy and Rhabdomyolysis

Advise patients that rosuvastatin tablets may cause myopathy and rhabdomyolysis. Inform patients that the risk is also increased when taking certain types of medication and they should discuss all medication, both prescription and over-the-counter, with their healthcare provider. Instruct patients to promptly report any unexplained muscle pain, tenderness or weakness particularly if accompanied by malaise or fever *[see Warnings and Precautions (5.1), and Drug Interactions (7.1)].*

Hepatic Dysfunction

Inform patients that rosuvastatin tablets may cause liver enzyme elevations and possibly liver failure. Advise patients to promptly report fatigue, anorexia, right upper abdominal discomfort, dark urine or jaundice *[see Warnings and Precautions (5.3)] .*

Inform patients that increases in HbA1c and fasting serum glucose levels may occur with rosuvastatin tablets. Encourage patients to optimize lifestyle measures, including regular exercise, maintaining a healthy body weight, and making healthy food choices *[see Warnings and Precautions (5.5)] .*

Pregnancy

Advise pregnant patients and patients who can become pregnant of the potential risk to a fetus. Advise patients to inform their healthcare provider of a known or suspected pregnancy to discuss if rosuvastatin tablets should be discontinued *[see Use in Specific Populations (8.1)] .*

Lactation

Advise patients that breastfeeding during treatment with rosuvastatin tablets is not recommended *[see Use in Specific Populations (8.2)] .*

Concomitant Use of Antacids

When taking rosuvastatin tablets with an aluminum and magnesium hydroxide combination antacid, administer rosuvastatin tablets at least 2 hours at least 2 hours before the antacid *[see Drug Interactions (7.2)] .*

Missed Doses

If a dose is missed, advise patients not to take an extra dose. Just resume the usual schedule *[see Dosage and Administration Information (2.1)] .*

Manufactured by:

Umedica Laboratories Pvt. Ltd.
Vapi, Gujarat 396195, INDIA (IND).

Distributed by:
Umedica Laboratories USA Inc.
Parsippany, NJ, 07054

Product of India

Revised: 10/26. V-02

PATIENT INFORMATION
ROSUVASTATIN (roe soo" va stat' in)
tablets, USP for oral use

Read this Patient Information carefully before you start taking rosuvastatin tablets and each time you get a refill. If you have any questions about rosuvastatin tablets, ask your healthcare provider. Only your healthcare provider can determine if rosuvastatin tablets are right for you.

What are rosuvastatin tablets?
Rosuvastatin tablets are a prescription medicine that contains a cholesterol-lowering medicine called rosuvastatin.

- Rosuvastatin tablets is used:
  - to reduce the risk of major adverse cardiovascular (CV) events, such as death from cardiovascular disease, heart attack, stroke, or the need for procedures to improve blood flow to the heart called arterial revascularization, in adults at increased risk for these events.
  - along with diet and exercise to lower the level of low-density lipoprotein (LDL-C) cholesterol or "bad" cholesterol:
    - in adults with primary hypercholesterolemia.
    - and slow the buildup of fatty deposits (plaque) in the walls of blood vessels in adults.
    - in adults and children 8 years of age and older with high blood cholesterol due to heterozygous familial hypercholesterolemia (HeFH) (an inherited condition that causes high levels of LDL-C).
    - in adults and children 7 years of age and older with homozygous familial hypercholesterolemia (HoFH) (an inherited condition that causes high levels of LDL-C).
  - along with diet for the treatment of adults with:
    - primary dysbetalipoproteinemia (an inherited condition that causes high levels of cholesterol and fat).
    - hypertriglyceridemia.

It is not known if rosuvastatin tablets is safe and effective in children younger than 8 years of age with HeFH or children younger than 7 years of age with HoFH or in children with other types of hypercholesterolemias (other than HeFH or HoFH).

Do not take rosuvastatin tablets if you:

- have liver problems.
- are allergic to rosuvastatin or any of the ingredients in rosuvastatin tablets. See the end of this leaflet for a complete list of ingredients in rosuvastatin tablets.

Before you take rosuvastatin tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have unexplained muscle aches or weakness.
- have or have had kidney problems.
- have or have had liver problems.

- drink more than 2 glasses of alcohol daily.
- have thyroid problems.
- are of Asian descent.
- are pregnant or think you may be pregnant, or are planning to become pregnant. If you become pregnant while taking rosuvastatin tablets, call your healthcare provider right away to discuss your rosuvastatin tablets treatment.
- are breastfeeding. Rosuvastatin can pass into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take rosuvastatin tablets. Do not breastfeed while taking rosuvastatin tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Tell your healthcare provider who prescribes rosuvastatin tablets if another healthcare provider increases the dose of another medicine you are taking. Rosuvastatin tablets may affect the way other medicines work, and other medicines may affect how rosuvastatin tablets works.
Especially tell your healthcare provider if you take:

- coumarin anticoagulants (medicines that prevent blood clots, such as warfarin)
- antacids (medicines you take for heartburn that contain aluminum and magnesium hydroxide
  Taking rosuvastatin tablets with certain medicines may increase the risk of muscle problems.

Especially tell your healthcare provider if you take:

- cyclosporine (a medicine for your immune system)
- teriflunomide (a medicine used to treat relapsing remitting multiple sclerosis)
- enasidenib (a medicine used to treat acute myeloid leukemia)
- capmatinib (a medicine for the treatment of non-small cell lung cancer)
- fostamatinib (a medicine used to treat low platelet counts)
- febuxostat (a medicine used to treat and prevent high blood levels of uric acid)
- gemfibrozil (a fibric acid medicine for lowering cholesterol)
- tafamidis [used to treat cardiomyopathy (enlarged and thickened heart muscle)]
- anti-viral medicines including certain HIV or hepatitis C virus drugs such as:
  - lopinavir, ritonavir, fosamprenavir, tipranavir, atazanavir, simeprevir
  - combination of
    - sofosbuvir/velpatasvir/voxilaprevir
    - dasabuvir/ombitasvir/paritaprevir/ritonavir
    - elbasvir/grazoprevir
    - sofosbuvir/velpatasvir
    - glecaprevir/pibrentasvir **and**
  - all other combinations with ledipasvir including ledipasvir/sofosbuvir
- darolutamide (a medicine for the treatment of prostate cancer)
- regorafenib (a medicine used to treat cancer of the colon and rectum)
- fibric acid derivatives (such as fenofibrate)
- ticagrelor (helps reduce the chance of a blood clot formation that can block a blood vessel)
- niacin or nicotinic acid
- colchicine (a medicine used to treat gout)
- belumosudil (used to treat chronic graft-versus-host disease)
- momelotinib (used to treat myelofibrosis, a rare form of blood cancer)
- vadadustat (medicine used to treat anemia caused by chronic kidney disease (CKD) in adults on dialysis for at least 3 months)

Ask your healthcare provider or pharmacist for a list of these medicines if you are not

sure. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get new medicine.

How should I take rosuvastatin tablets?

- Take rosuvastatin tablets exactly as your healthcare provider tells you to take it.
- Take rosuvastatin tablets, by mouth, 1 time each day, with or without food Swallow the tablet whole.
- Rosuvastatin tablets can be taken at any time of day, with or without food.
- **Do not**change your dose or stop rosuvastatin tablets without talking to your healthcare provider, even if you are feeling well.
- Your healthcare provider may do blood tests to check your cholesterol levels before and during your treatment with rosuvastatin tablets. Your healthcare provider may change your dose of rosuvastatin tablets if needed.
- While taking rosuvastatin tablets, continue to follow your cholesterol-lowering diet and to exercise as your healthcare provider told you to.
- If you take a medicine called an antacid that contains a combination of aluminum and magnesium hydroxide, take rosuvastatin tablets at least 2 hours before you take the antacid.
- If you miss a dose of rosuvastatin tablets, take your next dose at your normal scheduled time. **Do not take**an extra dose of rosuvastatin tablets.
- In case of an overdose, get medical help or contact a live Poison Center expert right away at 1-800-222-1222. Advice is also available online at poisonhelp.org.

What are the possible side effects of rosuvastatin tablets?
Rosuvastatin tablets may cause serious side effects, including:

- **Muscle pain, tenderness and weakness (myopathy).** Muscle problems, including muscle breakdown, can be serious in some people and rarely cause kidney damage that can lead to death. Tell your healthcare provider right away if:
  - you have unexplained muscle pain, tenderness, or weakness, especially if you have a fever or feel more tired than usual, while you take rosuvastatin tablets.
  - you have muscle problems that do not go away even after your healthcare provider has told you to stop taking rosuvastatin tablets. Your healthcare provider may do further tests to diagnose the cause of your muscle problems.

Your chances of getting muscle problems are higher if you:

- are taking certain other medicines while you take rosuvastatin tablets (see “Especially tell your healthcare provider if you take”)
- are 65 years of age or older
- are of Asian descent
- have thyroid problems (hypothyroidism) that are not controlled
- have kidney problems
- are taking higher doses of rosuvastatin tablets

- **Liver problems.**Your healthcare provider may do blood tests to check your liver before you start taking rosuvastatin tablets and if you have symptoms of liver problems while you take rosuvastatin tablets. Call your healthcare provider right away if you have any of the following symptoms of liver problems:
  - feel unusually tired or weak
  - loss of appetite
  - upper belly pain
  - dark urine
  - yellowing of your skin or the whites of your eyes

- **Protein and blood in the urine.**Rosuvastatin tablets may cause you to have protein and blood in your urine. If you develop protein or blood in your urine, your healthcare provider may decrease your dose of rosuvastatin tablets.

- **Increase in blood sugar (glucose) levels**. Rosuvastatin tablets may cause an increase in your blood sugar levels.

The most common side effects may include headache, nausea, muscle aches and pains, weakness, and constipation.
Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
For more information, ask your healthcare provider or pharmacist.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store rosuvastatin tablets?

- Store rosuvastatin tablets at room temperature, between 68°F to 77°F (20°C to 25°C) and in a dry place.

Keep rosuvastatin tablets and all medicines out of the reach of children.

General Information about the safe and effective use of rosuvastatin tablets
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use rosuvastatin tablets for a condition for which it was not prescribed. Do not give rosuvastatin tablets to other people, even if they have the same medical condition you have. It may harm them.
You can ask your pharmacist or healthcare provider for information about rosuvastatin tablets that is written for health professionals.

What are the Ingredients in rosuvastatin tablets?
Active Ingredient: rosuvastatin as rosuvastatin calcium USP
Inactive Ingredients: crospovidone USP, hypromellose USP, iron oxide red NF, lactose monohydrate USP, magnesium stearate USP, microcrystalline cellulose USP, sodium bicarbonate powder NF, titanium dioxide USP, triacetin USP.
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Manufactured by:
Umedica Laboratories Pvt. Ltd.
Vapi, Gujarat 396195, India (IND).

Distributed by:
Umedica Laboratories USA Inc.
Parsippany, NJ, 07054.

Product of India

This Patient Information has been approved by the U.S. Food and Drug Administartion.	Rev: 10/26. V-02

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

Rosuvastatin Tablets, USP 5 mg - NDC 60290-043-01 - 30s Bottle Label

Rosuvastatin Tablets, USP 10 mg - NDC 60290-044-01 - 30s Bottle Label

Rosuvastatin Tablets, USP 20 mg - NDC 60290-045-01 - 30s Bottle Label

Rosuvastatin Tablets, USP 40 mg - NDC 60290-046-01 - 30s Bottle Label

ROSUVASTATIN CALCIUM

rosuvastatin calcium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60290-044
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ROSUVASTATIN CALCIUM (UNII: 83MVU38M7Q) (ROSUVASTATIN - UNII:413KH5ZJ73)	ROSUVASTATIN	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics

Color	pink	**Score**	no score
Shape	ROUND	**Size**	5mm
Flavor		**Imprint Code**	R10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60290-044-01	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2026	
2	NDC:60290-044-02	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2025	
3	NDC:60290-044-03	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2025	
4	NDC:60290-044-04	100 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/15/2026	
5	NDC:60290-044-05	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207626	11/30/2025	

ROSUVASTATIN CALCIUM

rosuvastatin calcium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60290-043
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ROSUVASTATIN CALCIUM (UNII: 83MVU38M7Q) (ROSUVASTATIN - UNII:413KH5ZJ73)	ROSUVASTATIN	5 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	pink	**Score**	no score
Shape	ROUND	**Size**	4mm
Flavor		**Imprint Code**	R5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60290-043-01	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2026	
2	NDC:60290-043-02	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2025	
3	NDC:60290-043-03	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2025	
4	NDC:60290-043-04	100 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/15/2026	
5	NDC:60290-043-05	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207626	11/30/2025	

ROSUVASTATIN CALCIUM

rosuvastatin calcium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60290-045
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ROSUVASTATIN CALCIUM (UNII: 83MVU38M7Q) (ROSUVASTATIN - UNII:413KH5ZJ73)	ROSUVASTATIN	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics			
Color	pink	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	R20
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60290-045-01	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2026	
2	NDC:60290-045-02	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2025	
3	NDC:60290-045-03	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2025	
4	NDC:60290-045-04	100 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/15/2026	
5	NDC:60290-045-05	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207626	11/30/2025	

ROSUVASTATIN CALCIUM

rosuvastatin calcium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60290-046
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ROSUVASTATIN CALCIUM (UNII: 83MVU38M7Q) (ROSUVASTATIN - UNII:413KH5ZJ73)	ROSUVASTATIN	40 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics

Color	pink	**Score**	no score
Shape	OVAL	**Size**	11mm
Flavor		**Imprint Code**	R40
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60290-046-01	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2025	
2	NDC:60290-046-02	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2025	
3	NDC:60290-046-03	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2025	
4	NDC:60290-046-04	100 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/15/2026	
5	NDC:60290-046-05	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207626	11/30/2025	

Labeler - Umedica Laboratories USA Inc. (119579082)

Registrant - UMEDICA LABORATORIES PRIVATE LIMITED (920635096)

Establishment

Name	Address	ID/FEI	Business Operations
UMEDICA LABORATORIES PRIVATE LIMITED		920635096	analysis(60290-043, 60290-044, 60290-045, 60290-046) , manufacture(60290-043, 60290-044, 60290-045, 60290-046) , pack(60290-043, 60290-044, 60290-045, 60290-046)