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PATIENT INFORMATION

ROSUVASTATIN (roe soo" va stat' in) TABLETS USP

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 doctor. Only your doctor can determine if rosuvastatin tablets are right for you.

Patient Information available at https://umedicalabs.com/Rosuvastatin.html

What are rosuvastatin tablets?

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

- Rosuvastatin tablets is used to:
  - o reduce the risk of stroke, heart attack, and the need for procedures to improve blood flow to the heart called arterial revascularization in adults who do not have known heart disease but do have certain additional risk factors.
- Rosuvastatin tablets is used along with diet to:
  - o lower the level of low-density lipoprotein (LDL) cholesterol or "bad" cholesterol in adults with primary hyperlipidemia.
  - o slow the buildup of fatty deposits (plaque) in the walls of blood vessels.
  - o treat adults and children 8 years of age and older with high blood cholesterol due to heterozygous familial hypercholesterolemia (an inherited condition that causes high levels of LDL).
  - o along with other cholesterol lowering treatments or alone if such treatments are unavailable in adults and children 7 years of age and older with homozygous familial hypercholesterolemia (an inherited condition that causes high levels of LDL).
  - o treat adults with a type of high cholesterol called primary dysbetalipoproteinemia (type III hyperlipoproteinemia).
  - o lower the level of fat in your blood (triglycerides) in adults with hypertriglyceridemia.

The safety and effectiveness of rosuvastatin tablets has not been established in children younger than 8 years of age with heterozygous familial hypercholesterolemia or children younger than 7 years of age with homozygous familial hypercholesterolemia or in children with other types of hyperlipidemias (other than HeFH or HoFH).

Who should not take rosuvastatin tablets?

Do not take rosuvastatin tablet 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. Symptoms of allergic reactions include rash, itching, hives, and swelling.

What should I tell my doctor before and while taking rosuvastatin tablets?

Tell your doctor 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 65 years of age or older.
- 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. Breastfeeding is not recommended while taking rosuvastatin tablets.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking rosuvastatin tablets with certain other medicines may affect each other causing side effects. Rosuvastatin tablets may affect the way other medicines work, and other medicines may affect how rosuvastatin tablets works.

Especially tell your doctor if you take:

- cyclosporine (a medicine for your immune system)
- gemfibrozil (a fibric acid medicine for lowering cholesterol)
- fostamatinib (a medicine used to treat low platelet counts)
- febuxostat (a medicine used to treat and prevent high blood levels of uric acid)
- teriflunomide (a medicine used to treat relapsing remitting multiple sclerosis)
- capmatinib (a medicine for the treatment of non-small cell lung cancer)
- tafamidis (used to treat cardiomyopathy [enlarged and thickened heart muscle])
- darolutamide (a medicine for the treatment of prostate cancer)
- regorafenib (a medicine used to treat cancer of the colon and rectum)
- enasidenib (a medicine used to treat acute myeloid leukemia
- anti-viral medicines including certain HIV or hepatitis C virus drugs such as:
  - o lopinavir, ritonavir, fosamprenavir, tipranavir, atazanavir, simeprevir
  - o combination of
    - sofosbuvir/velpatasvir/voxilaprevir
    - dasabuvir/ombitasvir/paritaprevir/ritonavir
    - elbasvir/grazoprevir
    - sofosbuvir/velpatasvir
    - glecaprevir/pibrentasvir **and**
  - o all other combinations with ledipasvir including ledipasvir /sofosbuvir
- certain anti-fungal medicines (such as itraconazole, ketoconazole and fluconazole)
- coumarin anticoagulants (medicines that prevent blood clots, such as warfarin)
- niacin or nicotinic acid
- fibric acid derivatives (such as fenofibrate)
- colchicine (a medicine used to treat gout)

Ask your doctor 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 doctor and pharmacist when you get new medicine.

How should I take rosuvastatin tablets?

- Take rosuvastatin tablets exactly as your doctor tells you to take it.
- Take rosuvastatin tablets, by mouth, 1 time each day. 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 doctor, even if you are feeling well.
- Your doctor may do blood tests to check your cholesterol levels before and during your treatment with rosuvastatin tablets. Your doctor may change your dose of rosuvastatin tablets if needed.
- Your doctor may start you on a cholesterol lowering diet before giving you rosuvastatin tablets. Stay on this diet when you take rosuvastatin tablets.
- Wait at least 2 hours after taking rosuvastatin tablets to take an antacid that contains a combination of aluminum and magnesium hydroxide.
- 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.
- If you take too much rosuvastatin tablets or overdose, call your doctor or go to the nearest hospital emergency room right away.

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 doctor right away if:
  - o 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.
  - o you have muscle problems that do not go away even after your doctor has told you to stop taking rosuvastatin tablets. Your doctor may do further tests to diagnose the cause of your muscle problems.

Your chances of getting muscle problems are higher if you:

- o are taking certain other medicines while you take rosuvastatin tablets
- o are 65 years of age or older
- o have thyroid problems (hypothyroidism) that are not controlled
- o have kidney problems
- o are taking higher doses of rosuvastatin tablets

- **Liver problems**. Your doctor 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 doctor right away if you have any of the following symptoms of liver problems:
  - o feel unusually tired or weak
  - o loss of appetite
  - o upper belly pain
  - o dark urine
  - o 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 doctor 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, muscle aches and pains, abdominal pain, weakness, and nausea.

Tell your doctor if you have any side effect that bothers you or that does not go away.

For more information, ask your doctor 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.
- Safely throw away medicine that is out of date or no longer needed.

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 doctor 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, hypromellose, iron oxide red, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium bicarbonate powder, titanium dioxide, triacetin.

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Manufactured by:
Umedica Laboratories Pvt. Ltd.
Vapi, Gujarat 396195, India (IND).

Made in India

torrent PHARMA

Manufactured for:
TORRENT PHARMA INC. 8095014
Basking Ridge, NJ 07920.

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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SPECIFICATION FOR ARTWORK APPROVAL

Format No.: FM/PDD/002-01-05			Ref. SOP No.: PDD/002
Artwork/SAP Code No. : 205172		Old Version/SAP Code No. : 204989	Specification Version: 01
Product Name : Rosuvastatin Tablets 5 mg, 10 mg, 20 mg & 40 mg		~~Company Name~~/Country : Torrent Pharma - USA	
Component Type : Medication Guide		Pack Style : 30T, 90T & 500T	
Description : Incorparate: Add weblink : Patient Information available at https://umedicalabs.com/Rosuvastatin.html as per RA & Customer requirement.			
Specifications : L×H		Site : Umedica	
Full Size / Size	: 100x500 MM	Type / ~~Blister~~ / ~~Strip Size~~ / ~~Adhesive~~ / ~~Tube Type~~	: Front-Back
Size - Catch Cover / Foil / BOPP	: NA	~~Sachet Size~~/~~Pocket Size~~/Fold Size/~~Release Paper~~	: 100x50 MM
Space between Labels	: NA	Transparent Paper Thickness	: NA
GSM of Paper / ~~GSM of Aluminum Foil~~	: 28 GSM	Type of Paper / ~~GSM~~	: Bible Paper
Thickness of Foil	: NA	Type of Foil / Fold / Coating GSM	: NA
Cylinder	: NA	Lamination / Varnish / Material Grade	: NA
Repeat/Tolerence	: NA	Partition / Plate Size / Total GSM /	: NA
		Sealing / Embossing / Core Diameter	: NA
GSM/BF of Printed Shipper	: NA	Paper Grade / Flute Type / PLY of Shipper	: NA
(Top/Middle/Bottom and Flute layer	: NA		
Printing Colour	: Black		or as per Sample
Approved by Export/Marketing	:		[Approval attached with ADF]

CHECKLIST FOR CHECKING ARTWORK & SPECIFICATION

Brand Name and Generic Name(As per IP/BP/USP/ In-house Pharma-copeia)	Dosage Form and strength	Prefix Rx/ XRx	Mfg. Lic. No. / Code	Regulatory Agency Approval	Packing (Qty.) / Presentation	Dosage details if required	Size / Design	Composition /Label Claim	Schedule 'H','H1','G' or 'X' etc warning for local product / Red line for oral products	Item Code	QR Code/ Barcode (1D / 2D) as per requirement	Material and printing colours specifica-tion	Storage Condition as per pharmaco-peia/Buyer requirement/ Registration	Registration No. / Other requirement	Mfg. Name and Address, (Tel. No. and e-mail in the insert)	Marketed by / Distributors Name	Route of Admin. [in case of Inj./ Multidose Vial matter	Adequate Space (Batch details/2D barcode/ Embossing for Overprinting	Artwork Approved by Sign with Date
																			PDD Department
																			PPIC/Packing Department
																			QC Department
																			RA Department
																			QA Department

Note to Printer:

- **Return the original approved artwork along with the sample.**
- **The overprinting area should be unvarnished.**
- **Machine proof must be verified against the approved hard copy in Light, Standard and Dark shade should be certified and signed by an authorized person.**
- **Any deviation must be brought to the notice of the Packaging Development Department immediately in the writing.**
- **For any clarification, please contact Packaging Development Department.**