# **ROSUCOR TABLET**

Rosuvastatin Calcium (20 mg)

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### What Rosucor is used for?

Rosucor is used to lower high cholesterol levels. As changing your diet and taking more exercise were not enough to correct your cholesterol levels.

### **How Rosucor works**

Rosucor contains an active ingredient, rosuvastatin. Rosuvastatin belongs to a group of medicines called statins.

It works by helping to block your body's production of 'bad' cholesterol in the liver. It also improves your body's ability to remove it from your blood.

# Before you use Rosucor

- When you must not use it
- Do not take Rosucor:
- If you are allergic (hypersensitive) to Rosuvastatin, or to any of the ingredients.
- If you have liver disease.
- If you have severe kidney problems.
- If you have repeated or unexplained muscle aches or pains.
- If you take a medicine called ciclosporin
- Do not take Rosucor if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking Rosucor, stop taking it immediately and contact your doctor.
- If you are Breast-feeding; ask your doctor or pharmacist for advice before taking any medicine.

# - Before you start to use it

Take special care:

- If you have problems with your kidneys.
- If you are allergy to other statins.
- If you have problems with your liver.
- If you have had repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines.
- If you regularly drink large amounts of alcohol.

# - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if you are taking any of the following:

- Ciclosporin (used for example, after organ transplants).
- Protease inhibitors including ritonavir, atazanavir, lopinavir and/or tipranavir (antiviral medicines used to treat HIV/AIDS and hepatitis).
- Fibrates (such as gemfibrozil, fenofibrate) or any other medicines used to lower cholesterol (such as ezetimibe and niacin).
- Indigestion remedies (used to neutralise acid in your stomach).
- Erythromycin and Fusidic Acid (antibiotics)
- Medicines that could change Rosucor's effect or vice versa.
  - ✓ Warfarin (or any other medicine used for thinning the blood).
  - ✓ Oral contraceptive/hormone replacement therapy (HRT)

### How to use Rosucor

- How much to use
- The usual start dose is Rosucor 5-10 mg once daily and the majority of patients are controlled at this dose. A dose adjustment to 20 mg

- can be made after 4 weeks, if necessary.
- Rosuvastatin 40 mg should only be used in patients with severe high cholesterol level (including those with familial high cholesterol level) who do not achieve their treatment goal on 20 mg.
- Your doctor will decide the dose that suits you base on your condition

### - When to use it

Rosucor may be given at any time of day, with or without food.

### - How long to use it

Continue taking Rosucor for as long as your doctor recommends.

# - If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- <u>If you use too much (overdose)</u> Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

# While you are using it

- Things you must do
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Rosucor.
- Tell your doctor immediately if you become pregnant while taking this medication.
- Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever.

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■ Continue your diet control and exercise while you are taking Rosucor

### - Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Rosucor to anyone else, even if they have the same symptoms or condition as you.

# - Things to be careful of

Driving and using machines

Rosuvastatin is not expected to affect the ability to drive or use machines. If the tablets make you feel sick, dizzy or drowsiness or tired do not drive or use machines and contact your doctor immediately.

### **Side effects**

Like all medicines, Rosucor can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

- Hypersensitivity reactions including angioedema (severe swelling of the mucous membrane).
- Headache, dizziness, polyneuropathy (Symptoms are weakness, loss of sensation, pinsand-needle sensations or burning pain).
- Constipation, nausea, abdominal pain, inflammation of pancreas, diarrhea.
- Pruritus (Itching), rash, urticaria kind of skin rash.
- Stevens-Johnson syndrome (disorder of skin and mucous membranes).
- Aching muscles, muscle tenderness or weakness not caused by exercise, particularly if you also have a fever or generally feel unwell, rhabdomyolysis (damaged skeletal muscle tissue breaks down rapidly), joint pain

- Abnormal physical weakness or lack of energy, protein or blood in the urine.
- Jaundice, hepatitis (inflammation of liver), increase in liver enzymes.
- Memory loss, forgetfulness, memory impairment, confusion.
- high sugar in the blood, increased fasting blood sugar level

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

# Storage and Disposal of Rosucor

- Storage

Store below 30°C Protect from moisture and light. Keep out of reach of children.

## - <u>Disposal</u>

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **Product Description**

### - What it looks like

White to off white colored, round, biconvex, beveled edged film coated tablets with break line on one side and plain surface on other side.

## **Ingredients**

- Active ingredient

  Rosuvastatin Calcium
- Inactive ingredients
  Lactose Monohydrate
  Microcrystalline cellulose
  Crospovidone XL-10
  Magnesium stearate
  Hypromellose 2910
  Triacetin

# - <u>MAL number(s):</u> MAL10080065A

#### Manufacturer

Torrent Pharmaceuticals Ltd. Indrad 382 721, District: Mehsana India.

### **Product Registration Holder**

Laboratories Torrent (Malaysia) Sdn Bhd..

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# Date of revision

16/12/2015

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