

# VASTICURE-10 (Rosuvastatin Tablets 10mg)

Rosuvastatin Calcium (10mg)

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## What is VASTICURE-10 used for

VASTICURE-10 belongs to a group of medicines called statins. You have been prescribed this medicine because:

- You have a high cholesterol level. This means you are at risk from a heart attack or stroke. You have been advised to take a statin because changing your diet and taking more exercise were not enough to correct your cholesterol levels. You should continue with your cholesterol-lowering diet and exercise while you are taking VASTICURE-10.
- You have other factors that increase your risk of having a heart attack, stroke or related health problems. Heart attack, stroke and other problems can be caused by a disease called atherosclerosis. Atherosclerosis is due to build-up of fatty deposits in your arteries.

## How VASTICURE-10 works

VASTICURE-10 works by inhibiting an enzyme in your liver. This enzyme is responsible for cholesterol formation.

## Before you use VASTICURE-10

### -When you must not use it

Do not take this medicine:

- If you have ever had an allergic reaction to rosuvastatin or similar medicines or to any of its ingredients.
- If you are pregnant, trying to become pregnant or are breast-feeding. If you become pregnant while taking VASTICURE-10, stop taking it immediately and tell your doctor.
- 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 drug called ciclosporin (commonly used after organ transplants)
- If you are already on a cholesterol lowering medication of the fibrate class (e.g. gemfibrozil) or niacin.

If any of the above applies to you (or you are in doubt), please go back and see your doctor.

### -Before you start to use it

Talk to your doctor or pharmacist before taking VASTICURE-10:

- If you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition.

Take special care with VASTICURE-10 and tell your doctor or pharmacist:

- If you have ever been told that you have problems with your kidneys.
- If you have ever been told that you have problems with your liver.
- If you have had unexplained muscle aches or pains, a

history of muscle pains, or a previous history of muscle problems when taking other cholesterol lowering medicines.

- If you regularly drink large amounts of alcohol.
- If you take other medicines called fibrates (e.g. gemfibrozil) or niacin to lower your cholesterol.
- If you take medicines used to fight HIV infections (e.g. lopinavir/ritonavir, please see Taking other Medications)
- If you have high blood sugar or raised HbA1c.

### -Taking other medications

Tell your doctor or pharmacist if you are taking, or have recently taken any other medicines including any you bought without a prescription.

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

- Ciclosporin (commonly used after organ transplants)
- Warfarin (or any other drug that is used to thin the blood)
- Fibrates (such as gemfibrozil or fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe). Concurrent use with these medications can cause inflammation and degeneration of muscle tissue)
- Indigestion remedies (used to neutralize acid in your stomach)
- Erythromycin (an antibiotic)
- Medicines used to fight HIV infections (e.g. azatanavir, ritonavir)
- Medicines that reduce the action of vitamin K (e.g. vitamin K antagonists)

# VASTICURE-10 (Rosuvastatin Tablets 10mg)

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Please take special care with VASTICURE-10. The effects of these medicines could be changed by VASTICURE-10 or they could change the effects of VASTICURE-10.

## How to use VASTICURE-10

### -How much to use

Always take your medicine as your doctor has told you. You should check with your doctor or pharmacist if you are not sure what to do.

### Starting dose:

In adults treatment with rosuvastatin is usually started with the 10mg dose taken once daily, even if you have taken a higher dose of a different statin before. Some people may be asked to start treatment with one 5mg tablet taken once a day. The choice of your start dose will depend upon:

- Your cholesterol level.
- The level risk you have of experiencing a heart attack or stroke.
- Whether you may be more sensitive to possible side effects.

### Increasing the dose and maximum daily dose:

After checking the amount of lipids in your blood, your doctor may decide to increase your dose until you are taking the amount of VASTICURE-10 that is right for you. There will be a gap of four weeks between every dose adjustment.

In adults the maximum daily dose of VASTICURE-10 is 40mg. It is only for patients with high cholesterol levels and at high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 10mg. A dosage of 40mg once daily should only be initiated under specialist supervision.

In children 10-17 years of age, the maximum dose is 20mg. VASTICURE-10 should not be given

to children younger than 10 years.

### -When to use it

Swallow each table whole with a drink of water. Take VASTICURE-10 once daily. You can take it at any time of the day with or without food. Try to take your tablet at the same time every day to help you to remember to take it.

### -How long to use it

Do not stop taking your VASTICURE-10, even if you are feeling well, unless your doctor tells you to or unless you become pregnant. Talk to your doctor if you want to stop taking VASTICURE-10. Your cholesterol levels might increase again if you stop taking VASTICURE-10.

### -If you forget to use it

Don't worry, just take your next scheduled dose at the correct time.

Do not take a double dose to make up for the one you have missed.

### -If you use too much (overdose)

Contact your doctor or nearest hospital for advice.

## While you are using it

### -Things you must do

It is important to go back to your doctor for regular cholesterol checks, to make sure your cholesterol has reached and is staying at the correct level. Your doctor may decide to increase your dose so that you are taking the amount of VASTICURE-10 that is right for you.

### -Things you must not do

#### Pregnancy and breastfeeding:

Do not take VASTICURE-10 if you are pregnant, trying to become pregnant or are breastfeeding. If you become pregnant while taking VASTICURE-10, stop taking it immediately and tell your doctor. Ask your doctor or pharmacist for advice before taking any medicine.

### -Things to be careful of

#### Driving and using machines:

VASTICURE-10 is not expected to affect your ability to drive a car or to operate machinery.

### Side effects

Like all medicines, VASTICURE-10 can cause side effects although not everybody gets them.

It is important that you are aware of what these side effects may be. They are usually mild and disappear after a short time.

Stop taking VASTICURE-10 and seek medical help immediately if you have any of the following allergic reactions:

- Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat.
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing.
- Severe itching of the skin (with raised lumps)

Also, stop taking VASTICURE-10 and talk to your doctor immediately if you have any unusual aches and pains in your muscles which go on for longer than you might expect. Muscle symptoms are more common in children and adolescents than in adults. As with other statins, a very small number of people have experienced unpleasant muscle effects and rarely these have gone on to become a potentially life threatening muscle damage known as rhabdomyolysis.

If you have muscle problems that do not go away even after your doctor has told you to stop taking VASTICURE-10, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

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Common possible side effects:  
headache, muscle pain, stomach pain,  
general feeling of weakness,  
constipation, dizziness and feeling  
sick.

Unknown frequency:

- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness).

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of VASTICURE-10

### -Storage

Store below 30°C. Keep the medicine out of reach of children.

### -Disposal

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

Light pink coloured, round, biconvex and film coated tablets.

### -Ingredients

Active ingredient(s)  
Rosuvastatin calcium

Inactive ingredient(s)

Microcrystalline cellulose (PH102), pre-gelatinized starch, magnesium stearate, talc, colloidal anhydrous silica, opadry II pink 85G94028, purified water

### -MAL number

MAL21016010AZ

## Manufacturer

Gracure Pharmaceuticals Ltd.  
E-1105, Industrial Area,  
Phase-III Bhiwadi, Rajasthan, India

## Product Registration Holder

Healol Pharmaceuticals Sdn. Bhd.  
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