

# SYNERRV ROSUVASTATIN 5 SYNERRV ROSUVASTATIN 10 SYNERRV ROSUVASTATIN 20 (ROSUVASTATIN FILM-COATED TABLETS USP 5 MG/ 10 MG/ 20 MG)

Rosuvastatin Calcium equivalent to Rosuvastatin 5mg, 10mg and 20mg

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## What is SYNERRV ROSUVASTATIN used for

You have been prescribed SYNERRV ROSUVASTATIN because you have high cholesterol level. This means you are at risk from a heart attack or stroke.

## How SYNERRV ROSUVASTATIN works

SYNERRV ROSUVASTATIN is used to correct the levels of fatty substances in the blood called lipids, the most common of which is cholesterol.

There are different types of cholesterol found in the blood – ‘bad’ cholesterol (LDL-C) and ‘good’ cholesterol (HDL-C).

> SYNERRV ROSUVASTATIN can reduce the ‘bad’ cholesterol and increase the ‘good’ cholesterol.

> It works by helping to block your body’s production of ‘bad’

cholesterol. It also improves your body’s ability to remove it from your blood.

For most people, high cholesterol does not affect the way they feel because it does not produce any symptoms. However, if it is left untreated, fatty deposits can build up in the walls of your blood vessels causing them to narrow.

Sometimes, these narrowed blood vessels can get blocked which can cut off the blood supply to the heart or brain leading to a heart attack or stroke. By lowering your cholesterol levels, you can reduce your risk of having a heart attack, a stroke or related health problems.

You need to keep taking SYNERRV ROSUVASTATIN even if it has got your cholesterol to the right level, because it prevents cholesterol levels from creeping up again and causing build up of fatty deposits.

## Before you use SYNERRV ROSUVASTATIN

### -When you must not use it

Do not take SYNERRV ROSUVASTATIN:

> If you have ever had an allergic reaction to SYNERRV ROSUVASTATIN or similar medicines, or to any of its ingredients. SYNERRV ROSUVASTATIN contains lactose, which may cause a problem in small number of patients who are allergic to lactose.

> If you are pregnant, trying to become pregnant or are breast-feeding. If you become pregnant while taking SYNERRV ROSUVASTATIN stop taking it immediately and tell your doctor.

> If you have liver disease.

> If you have repeated or unexplained muscle aches or pains.

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

Take special care with SYNERRV ROSUVASTATIN 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 your thyroid gland is not working properly.

> If you take other medicines called fibrates to lower your cholesterol.

> If you take medicines used to fight the HIV infection alone or in combination e.g., lopinavir, ritonavir, atazanavir, simeprevir, sofosbuvir, velpatasvir, voxilaprevir, grazoprevir, elbasvir, ombitasvir, paritaprevir, dasabuvir, glecaprevir, pibrentasvir (used to treat infections including HIV or hepatitis C infections), regorafenib and darolutamide (used to treat cancer). Please see ‘Taking other medicines’.

> If you have high blood sugar or raised HbA<sub>1c</sub>.

> If you are over 70 (as your doctor needs to choose the right start dose of

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SYNERRV ROSUVASTATIN to suit you).

> If you have severe respiratory failure.

#### -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 (used for example, after organ transplants).

> Warfarin (or any other medicine used for thinning the blood).

> Fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe).

> Antacid (used to neutralize acid in your stomach).

> Erythromycin (an antibiotic), or medications used to fight the HIV infection – please see 'Before you start to use it'.

The effects of these medicines could be changed by SYNERRV ROSUVASTATIN or they could change the effects of SYNERRV ROSUVASTATIN.

This is not a complete list of medications to be careful with, please ask your doctor or pharmacist for further information.

#### **How to use SYNERRV ROSUVASTATIN**

##### -How much to use

Always take SYNERRV ROSUVASTATIN 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 SYNERRV 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 of 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 SYNERRV ROSUVASTATIN that is right for you. There will be a gap of four weeks between every dose adjustment.

In adults the maximum daily dose of SYNERRV ROSUVASTATIN 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 20mg. A dosage of 40mg once daily should only be initiated under specialist supervision.

In children 10-17 years of age, the maximum daily dose is 20mg. SYNERRV ROSUVASTATIN should not be given to children younger than 10 years.

##### -When to use it

Take SYNERRV ROSUVASTATIN once daily. You can take it in the morning or evening.

Try to take your tablet at the same time every day to help you to remember to take it.

##### *Regular cholesterol checks:*

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 SYNERRV ROSUVASTATIN that is right for you.

##### -How long to use it

Do not stop taking your SYNERRV ROSUVASTATIN, 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 SYNERRV ROSUVASTATIN. Your cholesterol levels might increase again if you stop taking SYNERRV ROSUVASTATIN.

##### -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)

If you take more SYNERRV ROSUVASTATIN than prescribed by your doctor, talk to your doctor or pharmacist straight away.

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## While you are using it

### -Things you must do

Take your medication daily as prescribed.

### -Things you must not do

Do not take other medications together with SYNERRV ROSUVASTATIN without speaking to your doctor or pharmacist first.

### -Things to be careful of

**Pregnancy and breast-feeding:** Do not take SYNERRV ROSUVASTATIN if you are pregnant, trying to become pregnant or are breast-feeding. If you become pregnant while taking SYNERRV ROSUVASTATIN stop taking it immediately and tell your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines:** SYNERRV ROSUVASTATIN is not expected to affect your ability to drive a car or to operate machinery.

## Side effects

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

It is important that you are aware of what these side effects may be.

Stop taking SYNERRV ROSUVASTATIN 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 SYNERRV ROSUVASTATIN and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than you might expect. 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 SYNERRV ROSUVASTATIN, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

### Common side effects:

> Headache  
> Muscle pain  
> Stomach pain  
> General feeling of weakness  
> Constipation  
> Dizziness  
> Feeling sick  
> An increase in the amount of protein in the urine – this usually returns to normal on its own without having to stop taking your Rosuvastatin tablets (only 40mg)

### Uncommon side effects:

> Skin rash  
> Itching  
> Hives  
> An increase in the amount of protein in the urine – this usually returns to normal on its own without

having to stop taking your SYNERRV ROSUVASTATIN tablets (only SYNERRV ROSUVASTATIN 5mg, 10mg and 20mg)

### Rare side effects:

> Severe allergic reaction – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, a severe itching of the skin (with raised lumps). If you think you are having an allergic reaction, stop taking SYNERRV ROSUVASTATIN and seek medical help immediately.  
> Muscle damage in adults – as a precaution, stop taking SYNERRV ROSUVASTATIN and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than expected.  
> A severe stomach pain (inflamed pancreas)  
> Increase in liver enzymes in the blood.

### Very rare side effects:

> Jaundice (yellowing of the skin and eyes)  
> Hepatitis (an inflamed liver)  
> Joint pain  
> Memory loss

### Side effects of unknown frequency:

> Sleep disturbances, including insomnia (difficulty in sleeping) and nightmares  
> Depression

Traces of blood in your urine (generally temporary and not associated with worsening kidney function). Increases in HbA<sub>1c</sub> (a measure of the average amount of sugar in your blood over time). If any of the side effects become troublesome, or if you experience

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any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 SYNERRV ROSUVASTATIN

#### -Storage

Keep out of reach and sight of children.

Do not use SYNERRV ROSUVASTATIN after the expiry date which is stated on the box/ blisters after EXP. The expiry date refers to the last day of the month.

Store your tablets below 30°C. Store in the original package.

#### -Disposal

Remember to return any unused medicine to your pharmacist (chemist).

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

SYNERRV ROSUVASTATIN 5: Pink 4.50 mm round, biconvex, beveled edge, film-coated tablets, debossed with 'R5' on one side.

SYNERRV ROSUVASTATIN 10: Pink, 5.50 mm round, biconvex,

beveled edge, film-coated tablets, debossed with 'R10' on one side.

SYNERRV ROSUVASTATIN 20: Pink, 7.00 mm round, biconvex, film-coated tablets, debossed with 'R20' on one side and plain on other side.

#### -Ingredients

##### · Active ingredient(s)

Rosuvastatin calcium equivalent to Rosuvastatin

##### · Inactive ingredient(s)

Lactose monohydrate, Microcrystalline cellulose, Sodium hydrogen carbonate, Crospovidone, Magnesium stearate (plant origin)

#### -MAL number

SYNERRV ROSUVASTATIN 5: MAL24056078AZ

SYNERRV ROSUVASTATIN 10: MAL24056077AZ

SYNERRV ROSUVASTATIN 20: MAL24056076AZ

### Manufacturer

Umedica Laboratories Pvt. Ltd., Plot No. 221, IInd Phase, G.I.D.C., Vapi, Gujarat, 396195, India

### Product Registration Holder

Synerrv Sdn. Bhd., SO-29-2, Menara 1, KL Eco City, Jalan Bangsar, Kg. Haji Abdullah Hukum, 59200 Kuala Lumpur, Malaysia

### Date of revision

-25/09/2024

### Serial Number

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