

## Package leaflet: Information for the patient

**Rosuva 5 mg Film-coated tablets**

**Rosuva 10 mg Film-coated tablets**

**Rosuva 20 mg Film-coated tablets**

**Rosuva 40 mg Film-coated tablets**

rosuvastatin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What Rosuva is and what it is used for
2. What you need to know before you take Rosuva
3. How to take Rosuva
4. Possible side effects
5. How to store Rosuva
6. Contents of the pack and other information

#### **1. What Rosuva is and what it is used for**

Rosuva belongs to a group of medicines called statins (HMG-CoA reductase inhibitors).

You have been prescribed Rosuva because:

- You have a **high cholesterol level**. This means you are **at risk from a heart attack or stroke**. Rosuva is used in adults, adolescents and children 6 years or older to treat high cholesterol.

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 Rosuva.

Or

- 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.

### **Why is it important to keep taking Rosuva?**

Rosuva 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 (low-density lipoprotein cholesterol, or LDL-C) and ‘good’ cholesterol (high-density lipoprotein cholesterol, or HDL-C).

- Rosuva can reduce the "bad" cholesterol and increase the "good" cholesterol.
- It works by helping to block your body’s production of ‘bad’ cholesterol and 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 a stroke. If you correct your cholesterol levels, you can reduce your risk of having 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** Rosuva, even if it has got your cholesterol to the right level, because **it prevents your cholesterol levels from creeping up again** and causing build-up of fatty deposits. However, you should stop if your doctor tells you to do so, or you have become pregnant.

## **2. What you need to know before you take Rosuva**

### **Do not take Rosuva:**

- If you are **allergic to rosuvastatin** or any of the other ingredients of this medicine (listed in section 6).
- If you are **pregnant** or **breast-feeding**. If you become pregnant while taking Rosuva **stop taking it immediately** and tell your doctor. Women should avoid becoming pregnant while taking Rosuva by using suitable contraception.
- If you have **liver disease**.
- If you have **severe kidney problems**.
- If you have **repeated or unexplained muscle aches or pains** (myopathy).
- If you take **a drug combination of sofosbuvir/velpatasvir/voxilaprevir** (used for viral infection of the liver called hepatitis C).
- If you take a medicine named **ciclosporin** (used, for example, after organ transplants).

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

**In addition, do not take the 40 mg dose of Rosuva (the highest dose):**

- If you have had **any repeated or unexplained muscle aches or pains** (myopathy), a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines
  - If you have **moderate kidney problems** (if you are in doubt, please ask your doctor)
  - If your **thyroid gland** is not working properly
  - If you **regularly drink large amounts of alcohol**
  - If you take **other medicines called fibrates** to lower your cholesterol
  - If **you are of Asian origin** – (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
- If any of the above applies to you (or you are in doubt), **please go back and see your doctor.**

### Warnings and precautions

Talk to your doctor or pharmacist before taking Rosuva:

- If you have **problems with your kidneys.**
- If you have **problems with your liver.**
- If you have **severe respiratory failure.**
- If you **have had repeated or unexplained muscle aches or pains** (myopathy), a personal or family history of muscle problems or a previous history of muscle problems when taking other cholesterol-lowering medicines. Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever. Also tell your doctor or pharmacist if you have a muscle weakness that is constant.
- 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 or lead to the occurrence of myasthenia (see section 4).
- 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 treat the HIV infection** (e.g. ritonavir with lopinavir, atazanavir and/or tipranavir), please see “Other medicines and Rosuva”.
- If you are taking or have taken in the last 7 days a medicine called **fusidic acid** (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and rosuvastatin can lead to serious muscle problems (rhabdomyolysis).
- If you are **over 70 years of age** (as your doctor needs to choose the right start dose of Rosuva to suit you).
- If you are of Asian origin – that is Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the right start dose of Rosuva to suit you.
- **If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking rosuvastatin or other related medicines.** Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with rosuvastatin treatment. Stop using Rosuva and seek medical attention immediately if you notice any of the symptoms described in section 4.

### Children and adolescents

- **If the patient is under 6 years old:** Rosuva should not be given to children younger than 6 years.

- **If the patient is below 18 years of age:** The Rosuva 40 mg is not suitable for use in children and adolescents below 18 years of age.

If any of the above applies to you (or if you are not sure):

- **Do not take Rosuva 40 mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of Rosuva.**

In a small number of people, statins can affect the liver. This is identified by a simple test which looks for increased levels of liver enzymes in the blood. For this reason, your doctor will usually carry out this blood test (liver function test) before and during treatment with Rosuva.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

### **Other medicines and Rosuva**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

**If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart Rosuva. Taking Rosuva with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.**

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

- **ciclosporin** (used for example, after organ transplants)
- **warfarin, ticagrelor or clopidogrel** or any other medicine used for thinning the blood
- **fibrates and other lipid-lowering products** (such as gemfibrozil, fenofibrate)
- **any other medicine used to lower cholesterol** (such as ezetimibe)
- **indigestion remedies** (used to neutralise acid in your stomach)
- **erythromycin** (an antibiotic)
- **an oral contraceptive** (the pill)
- **hormone replacement therapy**
- **regorafenib** (used to treat cancer)
- **darolutamide** (used to treat cancer)
- any of the following **medicines used to treat viral infections, including HIV or hepatitis C infection**, alone or in combination (please see “Warnings and precautions”): ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.

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

### **Rosuva with food and drink**

You can take Rosuva with or without food.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Do not take Rosuva** if you are pregnant or breast-feeding. If you become pregnant while taking Rosuva **stop taking it immediately** and tell your doctor. Women should avoid becoming pregnant while taking Rosuva by using suitable contraception.

### **Driving and using machines**

Most people can drive a car and operate machinery while taking Rosuva – it will not affect their ability. However, some people feel dizzy during treatment with Rosuva. If you feel dizzy, consult your doctor before attempting to drive or use machines.

### **Rosuva contains lactose and sodium**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

## **3. How to take Rosuva**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **Usual doses in adults**

#### **If you are taking Rosuva for high cholesterol:**

##### **Starting dose**

Your treatment with Rosuva must start with the **5 mg or the 10 mg dose**, even if you have taken a higher dose of a different statin before. 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 have a factor that may make you more sensitive to possible side effects.

Please check with your doctor or pharmacist which start dose of Rosuva will best suit you.

Your doctor may decide to give you the lowest dose (5 mg) if:

- you are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian)
- you are over 70 years of age
- you have moderate kidney problems
- you are at risk of muscle aches and pains (myopathy).

### **Increasing the dose and maximum daily dose**

Your doctor may decide to increase your dose. This is so that you are taking the amount of Rosuva that is right for you. If you started with a 5 mg dose, your doctor may decide to double this to 10 mg, then to 20 mg and then 40 mg if necessary. If you started on 10 mg, your doctor may decide to double this to 20 mg and then 40 mg if necessary. There will be a gap of four weeks between every dose adjustment.

The maximum daily dose of Rosuva is 40 mg. It is only for patients with high cholesterol levels and a high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 20 mg.

### **If you are taking Rosuva to reduce your risk of having a heart attack, stroke or related health problems:**

The recommended dose is 20 mg daily. However, your doctor may decide to use a lower dose if you have any of these factors mentioned above.

### **Use in children and adolescents aged 6 – 17 years**

The usual start dose is 5 mg. Your doctor may increase your dose to find the right amount of Rosuva for you. The maximum daily dose of Rosuva is 10 mg for children aged 6 to 9 years and 20 mg for children aged 10 to 17 years. Take your dose once a day. Rosuva **40 mg** tablet should **not** be used by children.

### **Taking your tablets**

Swallow each tablet whole with a drink of water.

Take Rosuva 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 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 Rosuva that is right for you.

### **If you take more Rosuva than you should**

Contact your doctor or nearest hospital for advice.

If you go into hospital or receive treatment for another condition, tell the medical staff that you're taking Rosuva.

### **If you forget to take Rosuva**

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Rosuva**

Talk to your doctor if you want to stop taking Rosuva. Your cholesterol levels might increase again if you stop taking Rosuva.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine 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 Rosuva 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)
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome).
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

**Also, stop taking Rosuva 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. 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*.
- lupus-like disease syndrome (including rash, joint disorders and effects on blood cells)
- muscle rupture.

**Common side effects** (may affect up to 1 in 10 people):

- headache
- dizziness
- constipation
- feeling sick
- stomach pain
- muscle pain
- feeling weak
- an increase in the amount of protein in the urine – this usually returns to normal on its own without having to stop taking your Rosuva tablets (only Rosuva 40 mg)
- diabetes – this is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

**Uncommon side effects** (may affect up to 1 in 100 people):

- rash, itching or other skin reactions

- an increase in the amount of protein in the urine – this usually returns to normal on its own without having to stop taking your Rosuva tablets (only Rosuva 5 mg, 10 mg and 20 mg).

**Rare side effects** (may affect up to 1 in 1,000 people):

- 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, then stop taking Rosuva** and seek medical help immediately
- muscle damage in adults – as a precaution, **stop taking Rosuva 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
- unusual bruising and bleeding due to low level of blood platelets.

**Very rare side effects** (may affect up to 1 in 10,000 people):

- jaundice (yellowing of the skin and eyes)
- hepatitis (an inflamed liver)
- traces of blood in your urine
- damage to the nerves of your legs and arms (such as numbness)
- joint pain
- memory loss
- gynecomastia (breast enlargement in men).

**Side effects of not known frequency** (frequency cannot be estimated from the available data):

- diarrhoea (loose stools)
- cough
- shortness of breath
- oedema (swelling)
- sleep disturbances, including insomnia and nightmares
- sexual difficulties
- depression
- breathing problems including persistent cough and/or shortness of breath or fever
- tendon disorders, sometimes complicated by rupture
- muscle weakness that is constant
- 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.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:



HPRA Pharmacovigilance; website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Rosuva**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton, after “EXP”. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Rosuva contains**

The active substance is rosuvastatin.

Each film-coated tablet contains 5 mg of rosuvastatin (as rosuvastatin calcium).

Each film-coated tablet contains 10 mg of rosuvastatin (as rosuvastatin calcium).

Each film-coated tablet contains 20 mg of rosuvastatin (as rosuvastatin calcium).

Each film-coated tablet contains 40 mg of rosuvastatin (as rosuvastatin calcium).

- The other ingredients are:

Tablet core: Lactose, Silica, Colloidal Anhydrous, Silicified Microcrystalline Cellulose, Maize Starch, Talc (E553b), Sodium Stearyl Fumarate.

Film-coating: Hypromellose, Mannitol (E421), Macrogol 6000, Talc (E553b), Titanium dioxide (E171), Ferric oxide, yellow (E172), Ferric oxide, red (E172).

### **What Rosuva looks like and contents of the pack**

*5 mg Film-coated tablets:*

Brown, round, film-coated tablets.

*10 mg Film-coated tablets:*

Brown, round, film-coated tablets with “RSV 10” debossed on one side.

*20 mg Film-coated tablets:*

Brown, round, film-coated tablets with “RSV 20” debossed on one side.

*40 mg Film-coated tablets:*

Brown, round, film-coated tablets with “RSV 40” debossed on one side.

The film-coated tablets are packed in OPA/Alu/PVC/Alu blisters and inserted in a carton.

Pack sizes:

20, 28, 60 film-coated tablets

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturers**

**Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland.

**Manufacturers**

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia.

Lek S.A., ul. Domaniewska 50 C, 02-672 Warsaw, Poland.

Lek S.A., ul. Podlipie 16C, PL-95 010 Stryków, Poland.

**This medicinal product is authorised in the Member States of the European Economic Area under the following names:**

Portugal: Rosuvastatina Hexal

Ireland: Rosuva 5 mg Film-coated tablets

Rosuva 10 mg Film-coated tablets

Rosuva 20 mg Film-coated tablets

Rosuva 40 mg Film-coated tablets

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