

## Package leaflet: information for the user

**Rosuvastatin Aurobindo 5 mg film-coated tablets**  
**Rosuvastatin Aurobindo 10 mg film-coated tablets**  
**Rosuvastatin Aurobindo 20 mg film-coated tablets**  
**Rosuvastatin Aurobindo 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 Rosuvastatin Aurobindo is and what it is used for
2. What you need to know before you take Rosuvastatin Aurobindo
3. How to take Rosuvastatin Aurobindo
4. Possible side effects
5. How to store Rosuvastatin Aurobindo
6. Contents of the pack and other information

### **1. What Rosuvastatin Aurobindo is and what it is used for**

Rosuvastatin Aurobindo belongs to a group of medicines called statins. You have been prescribed Rosuvastatin Aurobindo because:

- You have a **high cholesterol level**. This means you are **at risk from a heart attack or stroke**. Rosuvastatin Aurobindo 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 Rosuvastatin Aurobindo.

### **Why is it important to keep taking Rosuvastatin Aurobindo?**

Rosuvastatin Aurobindo 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).

- Rosuvastatin Aurobindo 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.

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 Rosuvastatin Aurobindo**, 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 Rosuvastatin Aurobindo

### Do not take Rosuvastatin Aurobindo:

- 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 Rosuvastatin Aurobindo **stop taking it immediately and tell your doctor**. Women should avoid becoming pregnant while taking Rosuvastatin Aurobindo 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.**
- **If you take a drug called 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 Rosuvastatin Aurobindo 40 mg (the highest dose):**

- **If you have moderate kidney problems** (if in doubt, please ask your doctor).
- **If your thyroid gland** is not working properly.
- **If you have had any 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.**
- **If you are of Asian origin** (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
- **If you take other medicines called fibrates** to lower your cholesterol.

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 Rosuvastatin Aurobindo:

- **If you have problems with your kidneys.**
- **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. Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever.
- **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. Please read this leaflet carefully, even if you have taken other medicines for high cholesterol before.

- **If you take medicines used to fight the HIV infection** e.g. lopinavir/ritonavir, please see section Other medicines and Rosuvastatin Aurobindo.
- **If you take antibiotics containing fusidic acid**, please see Other medicines and Rosuvastatin Aurobindo.

### **Children and adolescents**

- **If the patient is under 6 years old:** Rosuvastatin Aurobindo should not be given to children younger than 6 years.
- **If the patient is below 18 years of age:** The Rosuvastatin Aurobindo 40 mg tablet is not suitable for use in children and adolescents below 18 years of age.
- **If you are over 70** (as your doctor needs to choose the right start dose of Rosuvastatin Aurobindo to suit you)
- **If you have severe respiratory failure.**
- **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 Rosuvastatin Aurobindo to suit you.

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

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

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 Rosuvastatin Aurobindo.

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 Rosuvastatin Aurobindo**

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

Tell your doctor if you are taking any of the following: ciclosporin (used for example, after organ transplants), warfarin or clopidogrel (or any other drug used for thinning the blood), fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe), indigestion remedies (used to neutralise acid in your stomach), erythromycin (an antibiotic), fusidic acid (an antibiotic – please see Warnings and precautions), an oral contraceptive (the pill), hormone replacement therapy or lopinavir/ritonavir (used to fight the HIV infection – please see Warnings and precautions). The effects of these medicines could be changed by Rosuvastatin Aurobindo or they could change the effects of Rosuvastatin Aurobindo.

### **Rosuvastatin Aurobindo with food and drink**

You can take Rosuvastatin Aurobindo with or without food.

### **Pregnancy, breast-feeding and fertility**

Do not take Rosuvastatin Aurobindo if you are pregnant or breast-feeding.

If you become pregnant while taking Rosuvastatin Aurobindo **stop taking it immediately** and tell your doctor. Women should avoid becoming pregnant while taking Rosuvastatin Aurobindo by using suitable contraception.

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.

### **Driving and using machines**

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

**Rosuvastatin Aurobindo contains lactose.** If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

Rosuvastatin Aurobindo film-coated tablets contain allura red AC and sunset yellow FCF, which may cause allergic reactions.

## **3. How to take Rosuvastatin Aurobindo**

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

### **Recommended in adults**

**If you are taking Rosuvastatin Aurobindo for high cholesterol:**

#### **Starting dose**

Your treatment with Rosuvastatin Aurobindo 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 Rosuvastatin Aurobindo 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 Rosuvastatin Aurobindo that is right for you. If you started with a 5 mg dose, your doctor may decide to double this to 10 mg, then 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 Rosuvastatin Aurobindo is 40 mg. It is only for patients with high cholesterol levels and whose cholesterol levels are not lowered enough with 20 mg.

#### **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 Rosuvastatin Aurobindo for you. The maximum daily dose of Rosuvastatin Aurobindo 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. Rosuvastatin Aurobindo 40 mg tablet should not be used by children.

#### **Taking your film-coated tablets**

Swallow each tablet whole with a drink of water.

**Take Rosuvastatin Aurobindo once daily.** You can take it at any time of the day. 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 Rosuvastatin Aurobindo that is right for you.

#### **If you take more Rosuvastatin Aurobindo 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 Rosuvastatin Aurobindo.

#### **If you forget to take Rosuvastatin Aurobindo**

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 Rosuvastatin Aurobindo**

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

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 Rosuvastatin Aurobindo 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 Rosuvastatin Aurobindo 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*.

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

- Headache
- Stomach pain
- Constipation
- Feeling sick
- Muscle pain
- Feeling weak
- Dizziness
- 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 Aurobindo tablets (only Rosuvastatin Aurobindo 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 possible 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 Rosuvastatin Aurobindo tablets (only Rosuvastatin Aurobindo 5 mg, 10 mg and 20 mg).

**Rare possible side effects** (may affect up to 1 in 1000 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 Rosuvastatin Aurobindo and seek medical help immediately**
- Muscle damage in adults – as a precaution, **stop taking Rosuvastatin Aurobindo 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 possible 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
- Gynaecomastia (breast enlargement in men)

**Side effects of not known frequency may include:**

- Diarrhoea (loose stools)
- Stevens-Johnson syndrome (serious blistering condition of the skin, mouth, eyes and genitals)
- 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

### **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

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie)

e-mail: <mailto:medsafety@hpra.ie>.

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Rosuvastatin Aurobindo**

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

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from light.

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

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 Rosuvastatin Aurobindo contains**

The active substance is rosuvastatin. Each film-coated tablet contains 5 mg/ 10 mg/ 20 mg/ 40 mg of rosuvastatin (as rosuvastatin calcium).

The other ingredients are:

Tablet core: Lactose monohydrate, calcium hydrogen phosphate anhydrous, microcrystalline cellulose, crospovidone (type B), magnesium stearate.

Tablet film-coat: Hypromellose (15cP) (E464), lactose monohydrate, titanium dioxide (E171), sunset yellow FCF (E110), allura red AC aluminium lake (E129), indigo carmine aluminium lake (E132), triacetin.

### **What Rosuvastatin Aurobindo looks like and contents of the pack**

Rosuvastatin film-coated tablets 5 mg:

Pink coloured, oval shaped, biconvex film-coated tablets, debossed with 'J' on one side and '53' on the other side.

Rosuvastatin film-coated tablets 10 mg:

Pink coloured, round shaped, biconvex film-coated tablets, debossed with 'J' on one side and '54' on the other side.

Rosuvastatin film-coated tablets 20 mg:

Pink coloured, round shaped, biconvex film-coated tablets, debossed with 'J' on one side and '55' on the other side.

Rosuvastatin film-coated tablets 40 mg:

Pink coloured, oval shaped, biconvex film-coated tablets, debossed with 'J' on one side and '56' on the other side.

Rosuvastatin Aurobindo film-coated tablets are available in Polyamide /Al/PVC/ Aluminium blisters and HDPE bottle with polypropylene closure.

**Pack sizes:**

Blister:

5 mg, 10 mg & 20 mg: 10, 15, 20, 28, 30, 50, 56, 60, 90, 98 and 100.

40 mg: 15, 20, 28, 30, 50, 56, 60, 90, 98 and 100.

HDPE: 30, 100, 250 and 500.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Milpharm Limited  
Ares Block  
Odyssey Business Park  
West End Road  
Ruislip HA4 6QD  
United Kingdom

**Manufacturer**

Milpharm Limited  
Ares Block  
Odyssey Business Park  
West End Road  
Ruislip HA4 6QD  
United Kingdom

or

APL Swift Services (Malta) Limited  
HF26, Hal Far Industrial Estate, Hal Far  
Birzebbugia, BBG 3000  
Malta

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Belgium:	Rosuvastatin AB 5 mg/ 10 mg/ 20 mg/ 40 mg, filmomhulde tabletten
Cyprus:	Rosuvastatin Aurobindo 5 mg/ 10 mg/ 20 mg/ 40 mg επικαλυμμένο με λεπτό υμένιο δισκία
Czech republic	Rosuvastatin Aurobindo 10 mg/ 20 mg/ 40 mg Potahované tablety
Denmark:	Rosuvastatin "Orion"

Finland	Rosuvastatin Orion 5 mg/10 mg/ 20 mg/ 40 mg Tabletti, kalvopäällysteinen
France:	Rosuvastatine Arrow 5 mg/10 mg/20 mg, comprimé pelliculé
Germany:	Rosuvastatin Aurobindo 5 mg/ 10 mg/ 20 mg Filmtabletten
Ireland:	Rosuvastatin Aurobindo 5 mg/10 mg/ 20 mg/ 40 mg film-coated tablets
Latvia:	Rosuvastatin Aurobindo 5 mg/ 10 mg/ 20 mg/ 40 mg apvalkotās tabletes
Luxembourg:	Rosuvastatine AB 5 mg/ 10 mg/ 20 mg/ 40 mg, comprimé pelliculé
Malta	Rosuvastatin Aurobindo 5 mg/10 mg/ 20 mg/ 40 mg film-coated tablets
The Netherlands:	Rosuvastatin Aurobindo 5 mg/ 10 mg/ 20 mg/ 40 mg, filmomhulde tabletten
Poland	Rosuvastatin Aurobindo
Portugal:	Rosuvastatina Aurobindo
Romania	Rosuvastatina Aurobindo 5 mg/10 mg/ 20 mg/ 40 mg comprimate filmate
Sweden:	Rosuvastatin Orion 5 mg/ 10 mg/ 20 mg/ 40 mg filmdragerade tabletter
Spain:	Rosuvastatina Aurobindo 5 mg/ 10 mg/ 20 mg comprimidos recubiertos con película EFG
The United Kingdom:	Rosuvastatin 5 mg/ 10 mg/ 20 mg/ 40 mg film-coated tablets

**This leaflet was last revised in 02/2017.**