



PACKAGE LEAFLET: INFORMATION FOR THE USER

ZYROSA* 10/20/40

Rosuvastatin Tablets



Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

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

1) WHAT ZYROSA IS AND WHAT IT IS USED FOR

Zyrosa belongs to a group of medicines called statins.

You have been prescribed ZYROSA because:

- You have a high cholesterol level. This means you are at risk from a heart attack or stroke. Zyrosa 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 Zyrosa. 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 ZYROSA?

Zyrosa 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).

- Zyrosa 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 a 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 Zyrosa**, 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 ZYROSA

Do not take Zyrosa:

- **If you have ever had an allergic reaction to Zyrosa**, or to any of its ingredients.
- **If you are pregnant** or breast-feeding. If you become pregnant while taking Zyrosa **stop taking it immediately and tell your doctor**. Women should avoid becoming pregnant while taking Zyrosa 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 Zyrosa 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 Zyrosa.

- **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. Also tell your doctor or pharmacist if you have a muscle weakness that is constant.

- **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 treat the HIV infection** e.g. ritonavir with lopinavir and/or atazanavir, please see **Other medicines and Zyrosa**.
- **If you take antibiotics containing fusidic acid**, please see **Other medicines and Zyrosa**.

Children and adolescents

- **If the patient is under 6 years old:** Zyrosa should not be given to children younger than 6 years.
- **If the patient is below 18 years of age:** The Zyrosa 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 Zyrosa 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 Zyrosa to suit you.

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

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

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 Zyrosa.

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 Zyrosa

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 anti-viral medications such as ritonavir with lopinavir and/or atazanavir or simeprevir (used to treat infections, including HIV or hepatitis C infection – please see Warnings and precautions). The effects of these medicines could be changed by Zyrosa or they could change the effects of Zyrosa.

Pregnancy and breast-feeding

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

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

Driving and using machines

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

Zyrosa contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars (lactose or milk sugar), contact your doctor before taking Zyrosa. For a full list of ingredients please see **Contents of the pack and other information**.

3) HOW TO TAKE ZYROSA

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

Usual doses in adults

If you are taking Zyrosa for high cholesterol:

Starting dose

Your treatment with Zyrosa 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 Zyrosa 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 Zyrosa 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 Zyrosa 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 Zyrosa 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 the 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 Zyrosa for you. The maximum daily dose of Zyrosa 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. Zyrosa **40 mg tablet** should not be used by children.

Taking your tablets

Swallow each tablet whole with a drink of water.

Take Zyrosa 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 Zyrosa that is right for you.

If you take more Zyrosa 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 Zyrosa.

If you forget to take ZYROSA

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 ZYROSA

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

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 Zyrosa 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 Zyrosa 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 (these may affect between 1 in 10 and 1 in 100 patients):

- 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 Zyrosa tablets (only zyrosa 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 (these may affect between 1 in 100 and 1 in 1,000 patients):

- 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 Zyrosa tablets (only Zyrosa 10 mg and 20 mg).

Rare possible side effects (these may affect between 1 in 1,000 and 1 in 10,000 patients):

- 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 Zyrosa and seek medical help immediately**
- Muscle damage in adults – as a precaution, **stop taking Zyrosa 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 (these may affect less than 1 in 10,000 patients):

- 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
- Breast enlargement in men (gynaecomastia)

Side effects of unknown 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
- Tendon injury
- Muscle weakness that is constant

5. HOW TO STORE ZYROSA

Store below 30°C.

Protect from light and moisture

Keep out of reach of children.

- Do not use this medicine after the expiry date which is stated on the box/blisters after EXP. 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 ZYROSA contains:

The active substance in Zyrosa is rosuvastatin. Zyrosa film-coated tablets contain rosuvastatin calcium equivalent to 10 mg, 20 mg or 40 mg of rosuvastatin. The other ingredients are: lactose monohydrate, microcrystalline cellulose, tribasic calcium phosphate, croscopolidone, magnesium stearate, Opadry pink 02F84852 & purified water.

What ZYROSA looks like and contents of the pack

Zyrosa tablets are supplied in Alu/Alu blister packs of 2 x 14’s tablets.

Zyrosa comes in three tablet strengths:

Pink round shaped film coated tablet, debossed with “R 40” on one side and plain on other side.

Pink round shaped film coated tablet, debossed with “R 20” on one side and plain on other side.

Pink round shaped film coated tablet, debossed with “R 10” on one side and plain on other side.

Marketing Authorisation Holder and Manufacturer:

Oman Pharmaceutical Products Co., L.L.C.
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Salalah, Sultanate of Oman.

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