

ROSWERA

5mg or 10mg or 15mg or 20mg or 30mg or 40mg film-coated tablets

ROSUVASTATIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

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1. WHAT ROSWERA IS AND WHAT IS IT USED FOR

ROSWERA belongs to a group of medicines called statins. **You have been prescribed ROSWERA because:**

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

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 ROSWERA?

ROSWERA 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).

- ROSWERA 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 ROSWERA**, 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. BEFORE YOU TAKE ROSWERA

Do not take ROSWERA:

- **If you have ever had an allergic reaction to ROSWERA**, or to any of its ingredients.
 - **If you are pregnant** or breast-feeding. If you become pregnant while taking ROSWERA **stop taking it immediately and tell your doctor**. Women should avoid becoming pregnant while taking ROSWERA 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 ROSWERA 30mg or 40mg (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 ROSWERA.

- **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 ROSWERA**.
- **If you take antibiotics containing fusidic acid**, please see **Other medicines and ROSWERA**.

Children and adolescents

- **If the patient is under 6 years old:** ROSWERA should not be given to children younger than 6 years.
- **If the patient is below 18 years of age:** The ROSWERA 30mg and ROSWERA 40mg 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 ROSWERA 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 ROSWERA to suit you.

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

- **Do not take ROSWERA 30mg or 40mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of ROSWERA.**

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 ROSWERA.

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 ROSWERA

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 ROSWERA or they could change the effects of ROSWERA.

Pregnancy and breast-feeding

Do not take ROSWERA if you are pregnant or breast-feeding. If you become pregnant while taking ROSWERA **stop taking it immediately** and tell your doctor. Women should avoid becoming pregnant while taking ROSWERA 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 ROSWERA – it will not affect their ability. However, some people feel dizzy during treatment with ROSWERA. If you feel dizzy, consult your doctor before attempting to drive or use machines.

ROSWERA 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 ROSWERA.

3. HOW TO TAKE ROSWERA

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 ROSWERA for high cholesterol: Starting dose

Your treatment with ROSWERA 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 ROSWERA 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 ROSWERA 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 ROSWERA 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 ROSWERA 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 ROSWERA for you. The maximum daily dose of ROSWERA 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. ROSWERA 30mg and ROSWERA 40mg tablet should **not** be used by children.

Taking your tablets

Swallow each tablet whole with a drink of water.

Take ROSWERA 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 ROSWERA that is right for you.

If you take more ROSWERA 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 ROSWERA.

If you forget to take ROSWERA

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 ROSWERA

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

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 ROSWERA 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 ROSWERA 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 ROSWERA tablets (only ROSWERA 30mg and ROSWERA 40mg)
- 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 ROSWERA tablets (only ROSWERA 5 mg, 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 ROSWERA and seek medical help immediately**

- Muscle damage in adults – as a precaution, **stop taking ROSWERA 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

Reporting of side effects:

If you get any side effects talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ROSWERA

- Store below 30°C. Store in the original package in order to protect from moisture.
- 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 box/blisters/label 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.