

ROSUVASTATIN ASTRAZENECA

rosuvastatin

ROSUVASTATIN ASTRAZENECA 5 mg, 10 mg, 20 mg and 40 mg tablets (rosuvastatin)

Read all of this leaflet carefully before you start taking ROSUVASTATIN ASTRAZENECA

- **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.** 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

In this leaflet:

- 1) What is ROSUVASTATIN ASTRAZENECA and what is it used for?
- 2) Before you take ROSUVASTATIN ASTRAZENECA
- 3) How to take ROSUVASTATIN ASTRAZENECA
- 4) Possible side effects
- 5) How to store ROSUVASTATIN ASTRAZENECA
- 6) Further information

1. WHAT IS ROSUVASTATIN ASTRAZENECA AND WHAT IS IT USED FOR?

ROSUVASTATIN ASTRAZENECA belongs to a group of medicines called statins.

You have been prescribed ROSUVASTATIN ASTRAZENECA because:

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

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 ASTRAZENECA.

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 it is important to keep taking ROSUVASTATIN ASTRAZENECA

ROSUVASTATIN ASTRAZENECA 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 ASTRAZENECA 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 ROSUVASTATIN ASTRAZENECA**, 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 ROSUVASTATIN ASTRAZENECA

Do not take ROSUVASTATIN ASTRAZENECA:

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

Take special care with ROSUVASTATIN ASTRAZENECA

- **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 Taking other medicines.
- **If the patient is under 10 years old:** ROSUVASTATIN ASTRAZENECA should not be given to children younger than 10 years.
- **If the patient is below 18 years of age:** The ROSUVASTATIN ASTRAZENECA 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 ASTRAZENECA

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 ASTRAZENECA to suit you.

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

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

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 ASTRAZENECA.

Taking other medicines

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 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) an oral contraceptive (the pill), hormone replacement therapy or lopinavir/ritonavir (used to fight the HIV infection – please see Take special care with ROSUVASTATIN ASTRAZENECA). The effects of these medicines could be changed by ROSUVASTATIN ASTRAZENECA or they could change the effect of ROSUVASTATIN ASTRAZENECA.

Taking ROSUVASTATIN ASTRAZENECA with food and drink

You can take ROSUVASTATIN ASTRAZENECA with or without food.

Pregnancy and breast-feeding

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

Important information about some of the ingredients of ROSUVASTATIN ASTRAZENECA

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 ROSUVASTATIN ASTRAZENECA.

For a full list of ingredients please see *Further information* below.

3. HOW TO TAKE ROSUVASTATIN ASTRAZENECA

Always take ROSUVASTATIN ASTRAZENECA as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Usual doses in adults

If you are taking ROSUVASTATIN ASTRAZENECA for high cholesterol:

Starting dose

Your treatment with ROSUVASTATIN ASTRAZENECA 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 ASTRAZENECA 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 ASTRAZENECA 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 ASTRAZENECA 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 ROSUVASTATIN ASTRAZENECA 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.

Usual doses in children aged 10 – 17 years

The usual start dose is 5 mg. Your doctor may increase your dose to find the right amount of ROSUVASTATIN ASTRAZENECA for you. The maximum daily dose of ROSUVASTATIN ASTRAZENECA is 20 mg. Take your dose once a day. ROSUVASTATIN ASTRAZENECA **40 mg** tablet should **not** be used by children.

Taking your tablets

Swallow each tablet whole with a drink of water.

Take ROSUVASTATIN ASTRAZENECA 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 ASTRAZENECA that is right for you.

If you take more ROSUVASTATIN ASTRAZENECA 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 ASTRAZENECA.

If you forget to take ROSUVASTATIN ASTRAZENECA

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 missed.

If you stop taking ROSUVASTATIN ASTRAZENECA

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, ROSUVASTATIN ASTRAZENECA 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 ASTRAZENECA 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 ASTRAZENECA 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 ROSUVASTATIN ASTRAZENECA tablets (only ROSUVASTATIN ASTRAZENECA 40 mg).
- Diabetes in patients with elevated blood sugar levels

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 ROSUVASTATIN ASTRAZENECA tablets (only ROSUVASTATIN ASTRAZENECA 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 ROSUVASTATIN ASTRAZENECA and seek medical help immediately**
- Muscle damage in adults – as a precaution, **stop taking ROSUVASTATIN ASTRAZENECA 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

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

If any of the side effects become troublesome, or if you experience any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ROSUVASTATIN ASTRAZENECA

- Keep out of the reach and sight of children.
- Do not use ROSUVASTATIN ASTRAZENECA 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.
- Tablets should not be thrown in your bin or put down the drain. If they are out of date, or no longer suitable for you, return them to your pharmacist.
- Store your tablets below 30°C.
- If your tablets come in a plastic container, keep the lid tightly closed.
- Keep your tablets in the container you received them in.

6. FURTHER INFORMATION

What ROSUVASTATIN ASTRAZENECA contains:

The active substance in ROSUVASTATIN ASTRAZENECA is rosuvastatin. ROSUVASTATIN ASTRAZENECA film-coated tablets contain rosuvastatin calcium equivalent to 5 mg, 10 mg, 20 mg or 40 mg of rosuvastatin. The other ingredients are: lactose monohydrate, microcrystalline cellulose, calcium phosphate, crospovidone, magnesium stearate, hypromellose, triacetin, titanium dioxide (E171). ROSUVASTATIN ASTRAZENECA 10 mg, 20 mg and 40 mg film-coated tablets also contain red iron oxide (E172). ROSUVASTATIN ASTRAZENECA 5 mg film-coated tablets also contain yellow iron oxide (E172).

What ROSUVASTATIN ASTRAZENECA looks like and contents of the pack

ROSUVASTATIN ASTRAZENECA comes in blister packs containing 7, 14, 15, 20, 28, 30, 42, 50, 56, 60, 84, 90, 98 and 100 tablets and plastic containers with 30 and 100 tablets. (Not all packs are available in every country.)

ROSUVASTATIN ASTRAZENECA comes in four tablet strengths:

ROSUVASTATIN ASTRAZENECA 5 mg film-coated tablets are yellow, round and marked with ZD4522 and 5 on one side and plain on the reverse.

ROSUVASTATIN ASTRAZENECA 10 mg film-coated tablets are pink, round and marked with ZD4522 and 10 on one side and plain on the reverse.

ROSUVASTATIN ASTRAZENECA 20 mg film coated tablets are pink, round and marked with ZD4522 and 20 on one side and plain on the reverse.

ROSUVASTATIN ASTRAZENECA 40 mg film-coated tablets are pink, oval and marked with ZD4522 on one side and 40 on the reverse.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisations for ROSUVASTATIN ASTRAZENECA are held by AstraZeneca xxxx.

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This product is authorised in the Member States of the EEA under the following name(s):

ROSUVASTATIN ASTRAZENECA 5 mg, 10 mg, 20 mg and 40 mg (NL, IT), and 5 mg, 10 mg and 20 mg (DE).

This leaflet was last approved in mm/yyyy.

BLUE BOX FOR LOCAL REQUIREMENTS.

AstraZeneca [logo]