

Package leaflet: information for the user

Crestor 5, film-coated tablets 5 mg
Crestor 10, film-coated tablets 10 mg
Crestor 20, film-coated tablets 20 mg
Crestor 40, film-coated tablets 40 mg
Rosuvastatin

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm others, even if their symptoms 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.

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1. What is Crestor and what is it used for?

Crestor is a medicine that belongs to the group of statins.

Your doctor has prescribed Crestor for you because:

- You have high cholesterol in your blood. This means you have a higher risk of a heart attack or stroke. Crestor is used in adults, adolescents up to 18 years, and children from 6 years to treat high cholesterol.
- Increasing physical activity and changing your diet have not been enough to reduce the amount of cholesterol in your blood. Therefore, you have been advised to take a statin. While using Crestor, you should continue to increase physical activity and follow your diet.

Or:

- You have an increased risk of having a heart attack, stroke, or similar condition for another reason.

A heart attack, stroke, and other problems can result from a disease called atherosclerosis. Atherosclerosis is caused by the buildup of fatty substances in your arteries.

Why is it important for you to keep using Crestor?

Crestor is used to correct the amount of fatty substances in your blood, called lipids. The most common lipid is cholesterol.

There are different types of cholesterol in the blood – ‘bad’ cholesterol (LDL-C) and ‘good’ cholesterol (HDL-C).

- Crestor can lower the amount of ‘bad’ cholesterol and increase the amount of ‘good’ cholesterol.
- It works by inhibiting the production of ‘bad’ cholesterol in your body. It also improves your body's ability to remove ‘bad’ cholesterol from your blood.

Most people do not notice they have too much cholesterol because they have no symptoms. If you do nothing, fat can continue to stick to your blood vessels. Your blood vessels can become narrower as a result.

Sometimes these narrowed blood vessels can become blocked. Your blood may not flow well to your heart or brain. This can lead to a heart attack or stroke. By lowering the amount of cholesterol in your blood, you reduce your risk of having a heart attack, stroke, or similar condition.

It is important to keep using Crestor, even if the amount of cholesterol in your blood is back to normal. Continuing to use Crestor ensures that the amount of cholesterol in your blood does not rise again and prevents the buildup of fatty substances. You should stop using Crestor if your doctor tells you to, or if you become pregnant.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- If you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.
- If you are pregnant or breastfeeding. If you become pregnant while using Crestor, you must stop using it immediately. Inform your doctor. As a woman, you should avoid becoming pregnant while using Crestor. Therefore, you should use effective contraceptives.
- If you have liver disease.
- If you have severe kidney problems.
- If you often or unexpectedly suffer from muscle pain, muscle weakness, or muscle cramps.
- If you are using a combination of medicines containing sofosbuvir/velpatasvir/voxilaprevir (this is used against a viral infection of the liver called hepatitis C).
- If you are using the medicine ciclosporin (this is used, for example, after organ transplantation).
- If any of the above cases apply to you (or if you are not sure), contact your doctor.

Additionally, do not use Crestor 40 mg (the highest dosage):

- If you have moderate kidney problems (ask your doctor if you are not sure).

- If your thyroid is not functioning properly.
- If you have often or unexpectedly suffered from muscle pain, muscle weakness, or muscle cramps. If you or others in your family have had muscle problems or muscle problems due to using another medicine for high cholesterol.
- If you frequently drink large amounts of alcohol.
- If you are of Asian descent (from Japan, China, the Philippines, Vietnam, Korea, or India).
- If you are using fibrates. Fibrates are other medicines to lower the amount of cholesterol in your blood.
- If any of the above points apply to you (or if you are not sure), contact your doctor.

When should you be extra careful with this medicine?

- If you have problems with your kidneys.
- If you have problems with your liver.
- If you have often or unexpectedly suffered from muscle pain, muscle weakness, or muscle cramps. If you or others in your family have had muscle problems or muscle problems due to the use of another medicine for high cholesterol. If you have unexpected muscle pain, muscle weakness, or muscle cramps, especially if you feel unwell or have a fever, you should tell your doctor immediately. Also inform your doctor or pharmacist if you constantly suffer from muscle weakness.
- if you have or have had myasthenia (a disease where general muscle weakness occurs, in some cases also in muscles used for breathing) or ocular myasthenia (a disease that causes eye muscle weakness), as statins can sometimes worsen the condition or lead to the occurrence of myasthenia (see section 4).
- If you have ever had a severe skin rash or skin peeling, blistering and/or mouth sores after taking Crestor or other related medicines.
- If you regularly drink large amounts of alcohol.
- If your thyroid is not functioning properly.
- If you are using fibrates. Fibrates are other medications to lower the amount of cholesterol in your blood. Read this leaflet carefully, even if you have previously used other medications for high cholesterol.
- If you are using medications for an HIV infection, such as ritonavir with lopinavir and/or atazanavir. See "Are you using any other medications?"
- If you are currently using, or have used in the last 7 days, a medication called fusidic acid (used against bacterial infections), orally (by mouth) or injected. The combination of fusidic acid and Crestor can lead to serious muscle problems (rhabdomyolysis). See "Are you using any other medications?"
- If you are over 70 years old (because your doctor needs to choose the appropriate starting dose of Crestor for you).
- If you have severely impaired lung function.
- If you are of Asian descent – that is, originating from Japan, China, the Philippines, Vietnam, Korea, or India. Your doctor needs to choose the appropriate starting dose of Crestor for you.

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

- Then you should not take Crestor 40 mg (the highest dosage). You must first ask your doctor or pharmacist if you can use Crestor.

Severe skin reactions, including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported in connection with

treatment with Crestor. Stop using Crestor and seek immediate medical help if you experience any of the complaints described in section 4.

In a small number of people, statins can cause their liver to function differently. Your doctor can check this with a simple test. This test shows whether the amount of liver enzymes in your blood is elevated. Therefore, your doctor may perform this blood test (liver function test) before you receive Crestor and during your treatment with Crestor.

During the period you are using this medication, your doctor will closely monitor whether you have diabetes or are at increased risk of developing diabetes. You may be at increased risk of developing diabetes if you have high sugar and fat levels in your blood, if you are overweight, and if you have high blood pressure.

Children and adolescents up to 18 years old

- If the patient is younger than 6 years: Crestor should not be given to children younger than 6 years.
- If the patient is younger than 18 years: The Crestor 40 mg tablet (highest strength) is not suitable for use in children and adolescents up to 18 years.

Are you using any other medications?

Are you using any other medications besides Crestor, have you done so recently, or are you planning to do so soon? Then tell your doctor or pharmacist. This also applies to medications for which you do not need a prescription.

Tell your doctor if you are using any of the following medications:

- ciclosporin (used, for example, after organ transplants)
- warfarin, clopidogrel or ticagrelor (or another medicine used for blood thinning)
- fibrates (such as gemfibrozil or fenofibrate) or another medicine used to lower the amount of cholesterol in your blood (such as ezetimibe)
- agents for stomach or intestinal problems (to reduce the acid in your stomach)
- erythromycin (antibiotics), fusidic acid (antibiotics – see below and When to be extra careful with this medicine)
- an oral contraceptive (the pill)
- regorafenib (used to treat cancer)
- darolutamide (used to treat cancer)
- capmatinib (used to treat cancer)
- hormone treatment
- fostamatinib (used to treat a reduced number of platelets)
- febuxostat (used to treat and prevent high levels of uric acid in the blood)
- teriflunomide (used to treat multiple sclerosis)
- leflunomide (used for the treatment of rheumatoid arthritis),
- medicines to treat viral infections such as HIV or a hepatitis C infection. This may be when used alone or in combination with another medicine (see When to be extra careful with this medicine?). These include the following medicines: ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir or pibrentasvir.
- Roxadustat or vadadustat (used for the treatment of anemia in patients with chronic kidney disease),
- tafamidis (used for the treatment of a disease called transthyretin amyloidosis)

- momelotinib (used for the treatment of myelofibrosis in adults with anemia). The effect of these medicines could be altered by Crestor. These medicines could also alter the effect of Crestor.

If you need to take oral fusidic acid to treat a bacterial infection, you must temporarily stop using this medicine. Your doctor will tell you when it is safe to resume using Crestor. The simultaneous use of Crestor and fusidic acid can in rare cases lead to muscle weakness, tenderness, or pain (rhabdomyolysis). For more information on rhabdomyolysis, see section 4.

What should you pay attention to with food and drink?
You can take Crestor with or without food.

Pregnancy and breastfeeding

Do not use Crestor if you are pregnant or breastfeeding. If you become pregnant while using Crestor, you must stop using it immediately. Inform your doctor. As a woman, you should avoid becoming pregnant while using Crestor. Therefore, you should use effective contraceptives.

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

Driving and using machines

Most people can drive and use machines while using Crestor. Some people do feel dizzy while using Crestor. If you feel dizzy, you should ask your doctor whether you can drive or use machines.

Crestor contains lactose

If your doctor has told you that you cannot tolerate certain sugars (lactose or milk sugar), contact your doctor before using this medication.

For a complete list of ingredients in this medication, see the section Contents of the package and other information.

3. How to use this medication?

Always use this medication exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The recommended dosage for adults

If you are using Crestor to lower your cholesterol:

Starting dose

You should start with Crestor 5 mg or 10 mg, even if you have previously used a higher dose of another statin. The choice of your starting dose depends on:

- The amount of cholesterol in your blood.
- Your risk of having a heart attack or stroke.
- Whether you are sensitive to possible side effects.

Ask your doctor or pharmacist which starting dose of Crestor is right for you. Your doctor may decide to give you the lowest dose (5 mg) if:

- You are of Asian descent (from Japan, China, the Philippines, Vietnam, Korea, or India).
- You are over 70 years old.
- You have moderate kidney problems.
- You have a risk of developing muscle pain, muscle weakness, or muscle cramps (myopathy).

Increasing the dosage and the highest dosage per day

Your doctor may decide to increase your dosage. Your doctor will ensure that you use the amount of Crestor that is right for you. If you started with a dosage of 5 mg, your doctor may decide to double it to 10 mg, then to 20 mg, and then to 40 mg if necessary. If you started with 10 mg, your doctor may decide to double it to 20 mg and then to 40 mg if necessary. There is a four-week interval between each adjustment.

The highest daily dosage of Crestor is 40 mg. This dosage is only for patients with a lot of cholesterol in their blood and for patients who have a high risk of having a heart attack or stroke. You may receive 40 mg if the amount of cholesterol in your blood is not sufficiently reduced with 20 mg.

If you are using Crestor to reduce your risk of having a heart attack, stroke, or similar condition:

The recommended dosage is 20 mg per day. However, your doctor may decide to give you a lower dosage if any of the above conditions apply to you.

Use in children and adolescents aged 6 to 17 years

The dosage for children and adolescents aged 6 to 17 years varies from 5 to 20 mg once a day. The usual starting dosage is 5 mg per day, and your doctor may gradually increase this dosage to find the one that best suits you. The maximum daily dosage of Crestor is 10 or 20 mg for children and adolescents aged 6 to 17 years, depending on the underlying condition being treated. Take your dosage once a day. The Crestor 40 mg tablet should not be given to children.

Taking your tablets

Swallow each tablet whole with some water.

Take Crestor once a day. You can take it at any time of the day. Try to take your tablets at the same time each day. This helps you not to forget to take them.

Regular checks of the amount of cholesterol in your blood

It is important that you regularly visit your doctor to check the amount of cholesterol in your blood. Your doctor will then see if the amount of cholesterol in your blood is good and remains good. Your doctor may decide to give you a higher dosage so that you take the amount of Crestor that is right for you.

Have you taken too much of this medicine?

Ask your doctor or the nearest hospital for advice.

If you are admitted to the hospital or treated for something else, you must tell the medical staff that you are using Crestor.

Have you forgotten to take this medicine?

You do not need to worry, just take your next dose at the correct time. Do not take a double dose to make up for the forgotten dose.

If you stop taking this medicine

Talk to your doctor if you want to stop using Crestor. The amount of cholesterol in your blood may rise again if you stop using Crestor.

Do you have any other questions about using this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can have side effects. Not everyone gets them. It is important that you know what these side effects can be. They are usually mild and go away after a short time.

Stop using Crestor and seek advice from your doctor immediately if you experience any of the following allergic reactions:

- Difficulty breathing, with or without swelling of your face, lips, mouth, and/or throat.
- Swelling of your face, lips, tongue, and/or throat, which may cause difficulty swallowing.
- Severe itching of your skin (with bumps).
- Reddish, non-raised, round spots in the shape of a target on the trunk, often with central blisters, skin peeling, sores in the mouth, throat, nose, genitals, and eyes. This severe skin rash may be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome).
- Widespread skin rash, high body temperature, and enlarged lymph nodes (DRESS syndrome or drug-induced hypersensitivity).

Also stop using Crestor and seek advice from your doctor immediately:

- if you experience unexpected muscle pain, muscle weakness, or muscle cramps that last longer than you would expect. These muscle complaints are more common in children and adolescents up to 18 years than in adults. As was the case with other statins, a small number of people have experienced unpleasant muscle problems. In rare cases, these muscle problems have led to serious muscle damage (also known as rhabdomyolysis) which can be life-threatening.
- if you have a muscle rupture.
- if you experience lupus-like syndrome (including rash, joint abnormalities, and effects on blood cells).

Common (between 1 in 10 and 1 in 100 patients) possible side effects:

- Headache; stomach pain; constipation; nausea; muscle pain; feeling of weakness; dizziness.
- An increase in the amount of protein in your urine – this usually returns to normal on its own without you having to stop using your Crestor tablets (only Crestor 40 mg).
- Diabetes. You are at greater risk of this if you have high blood sugar and fat levels, if you are overweight and if you have high blood pressure. Your doctor will monitor you during the period you are using this medication.

Uncommon (between 1 in 100 and 1 in 1,000 patients) possible side effects:

- Rash, itching, or other skin reactions.

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

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

- Severe allergic reaction – you may notice this by, for example, swelling of your face, lips, tongue and/or throat, difficulty swallowing and breathing, intensely itchy skin (with bumps). If you think you are having an allergic reaction, stop taking Crestor and seek medical help immediately.
- Muscle damage in adults – to be safe, you should stop taking Crestor and ask your doctor for advice immediately if you have unexpected problems or pain in your muscles that last longer than you would expect.
- Severe abdominal pain (inflamed pancreas).
- Increase in liver enzymes in your blood.
- Bleeding or bruising occurs more easily than normal due to a shortage of blood platelets.
- The lupus-like syndrome (including rash, joint abnormalities, and effects on blood cells).

Very rare (in less than 1 in 10,000 patients) possible side effects:

- Jaundice (yellowing of your skin and eyes); hepatitis (liver inflammation); traces of blood in your urine; nerve damage in your arms and legs (such as numbness); joint pain; memory loss and breast enlargement in men (gynecomastia).

Side effects of unknown frequency:

- Diarrhea (loose stools); cough; shortness of breath; fluid retention (edema); sleep disorders, such as insomnia and having nightmares; sexual problems; (severe) depression; breathing problems, such as a persistent cough and/or shortness of breath or fever; tendon injury and constant muscle weakness.
- Myasthenia gravis (a disease causing general muscle weakness, in some cases in muscles used for breathing); ocular myasthenia (a disease causing eye muscle weakness). Contact your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping eyelids, difficulty swallowing, or shortness of breath.

Reporting side effects:

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Blisters: Store below 30 °C. Keep in the original packaging to protect from moisture.

Plastic bottle: Store below 30 °C. Keep the bottle tightly closed to protect from moisture.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box, blisters/label after EXP. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

The active substance in this medicine is rosuvastatin. Crestor film-coated tablets contain rosuvastatin calcium equivalent to 5 mg, 10 mg, 20 mg, or 40 mg of rosuvastatin.

The other substances in this medicine are lactose monohydrate, microcrystalline cellulose, calcium phosphate, crospovidone, magnesium stearate, hypromellose, triacetin, and titanium dioxide (E171).

Crestor 10 mg, 20 mg, and 40 mg film-coated tablets also contain red iron oxide (E172). Crestor 5 mg film-coated tablets also contain yellow iron oxide (E172).

What does Crestor look like and what is in a package?

Crestor is available in a package with aluminum blister strips containing 7, 14, 15, 20, 28, 30, 42, 50, 56, 60, 84, 90, 98, and 100 tablets and plastic bottles with 30 and 100 tablets. (Not all pack sizes may be marketed.)

Crestor is available in tablets with 4 different strengths:

Crestor 5 mg film-coated tablets are yellow, round, and marked with ZD4522 and 5 on one side and are smooth on the other side.

Crestor 10 mg film-coated tablets are pink, round, and marked with ZD4522 and 10 on one side and are smooth on the other side.

Crestor 20 mg film-coated tablets are pink, round, and marked with ZD4522 and 20 on one side and are smooth on the other side.

Crestor 40 mg film-coated tablets are pink, oval, and marked with ZD4522 on one side and 40 on the other side.

Marketing authorization holder and manufacturer

The marketing authorizations for Crestor are held by:

Grünenthal B.V.

De Corridor 21K

3621 ZA Breukelen

Manufacturer responsible for batch release:

AstraZeneca AB, Gärtunavägen Södertälje, 152-57, Sweden

Grünenthal GmbH, Zieglerstraße 6, 52078 Aachen, Germany

Farmaceutici Formenti S.p.A., Via Di Vittorio 2, 21040 Origgio (VA), Italy

This product is registered under:

RVG 30823 (Crestor 5);

RVG 26872 (Crestor 10);

RVG 26873 (Crestor 20);

RVG 26874 (Crestor 40).

This medicine is registered in member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:
Crestor 5, 10, 20, and 40 (NL, AT, BE, DK, GR, FI, IC, IE, IT, LU, NO, MT, PL, PT, SE (Northern Ireland)), and 5 mg, 10 mg, and 20 mg (DE, ES, FR).

This leaflet was last approved in 10/2025

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