PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

CRESAGEN 5 mg film coated tablets

CRESAGEN 10 mg film coated tablets

CRESAGEN 20 mg film coated tablets

CRESAGEN 40 mg film coated tablets

Rosuvastatin Calcium

Contains sugar (lactose monohydrate)

Each 5 mg film-coated tablet contains 45,72 mg lactose monohydrate.

Each 10 mg film-coated tablet contains 90,90 mg lactose monohydrate.

Each 20 mg film-coated tablet contains 181,80 mg lactose monohydrate.

Each 40 mg film-coated tablet contains 233,005 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking CRESAGEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CRESAGEN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CRESAGEN is and what it is used for

CRESAGEN contains 5 mg, 10 mg, 20 mg or 40 mg of rosuvastatin, as rosuvastatin calcium, per film-coated tablet and belongs to the pharmacotherapeutic group called HMG-CoA reductase inhibitors.

CRESAGEN is used, together with diet, to lower high levels of fats in the blood, which are called lipids, usually when changes to diet and exercise have failed to do this. CRESAGEN, in addition to diet, lowers “bad” cholesterol (LDL) and increases “good” cholesterol (HDL) in the blood.

CRESAGEN is also used to reduce total cholesterol and “bad” cholesterol (LDL) in adult patients with very high cholesterol and a family history of high cholesterol, either alone or together with diet and other lipid lowering treatments.
CRESAGEN 40 mg should only be considered in patients with severe high cholesterol and high cardiovascular risk who do not achieve their treatment goal on 20 mg of CRESAGEN or alternative therapy.

Specialist supervision is recommended when the 40 mg dose is initiated.

2. What you need to know before you take CRESAGEN

Do not take CRESAGEN:

- if you are hypersensitive (allergic) to rosuvastatin calcium or any of the other ingredients of CRESAGEN (listed in section 6).

- if you currently have a liver disease
- if you have severe kidney problems
- if you take a medicine called ciclosporin (used, for example, after organ transplants) (see Other Medicines and CRESAGEN)
- if you are pregnant or breastfeeding or if you are a woman of childbearing potential not using appropriate contraceptive measures (see Pregnancy, breastfeeding and fertility)
- if you have myopathy or any disease of the muscle.
- children as safety and efficacy have not been demonstrated.

Warnings and precautions

Special care should be taken with CRESAGEN:

- if you if you consume excessive quantities of alcohol and/or have a history of liver disease.
- if you have muscle pain/disease
- if you are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean andIndian).
- if you are over 70 years of age.
- if you have an underactive thyroid gland
- if you take protease inhibitors (used in the treatment of HIV infections).
- serious liver problems may occur. You should therefore notify your medical practitioner right away if you have the following symptoms: unusual fatigue or weakness; loss of appetite; stomach pain; dark-coloured urine; or yellowing of the skin or the whites of the eyes. Your doctor will carry out a liver function test before treatment starts and if needed thereafter.
- you may experience increase in blood sugar levels.
- if you are taking fibrates (cholesterol lowering medicine) please see **Other medicine and CRESAGEN**
- if you are taking or have taken in the last 7 days a medicine called fusidic acid (a medicine for bacterial infection), orally or by injection. The combination of fusidic acid and CRESAGEN

can lead to serious muscle problems (rhabdomyolysis), please see **Other medicine and CRESAGEN**

- if you are taking other HMG-CoA reductase inhibitors together with fibric acid derivatives including gemfibrozil, ciclosporin, nicotinic acid, azole antifungals, protease inhibitors (such as lopinavir/ritonavir – medicines used to treat HIV infection) and macrolide antibiotics (see **Other medicine and CRESAGEN**).

CRESAGEN may cause interstitial lung disease, especially with long-term treatment. Tell your doctor if you experience difficulty breathing, develop a non-productive cough and/or deterioration in general health (e.g. fatigue, weight loss and fever) while taking CRESAGEN.

In a small number of people, CRESAGEN can affect the liver. This is identified by a 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 treatment starts with CRESAGEN, and if needed thereafter.

In patients whose high cholesterol is caused by another disease, such as thyroid or kidney problems, the underlying disease should be treated prior to initiating therapy with CRESAGEN.

While you are on CRESAGEN 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. CRESAGEN should be used with care in patients with Type 2 diabetes and in patients at risk.

Please consult your doctor if these statements were applicable to you any time in the past.

Other medicines and CRESAGEN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

Contraindicated combinations

CRESAGEN should not be used together with ciclosporin (used for example, after organ transplants).

The 40 mg dose is contraindicated with concomitant use of a fibrate.

There may be a higher than usual chance of other side effects

Fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe) may increase the effect of CRESAGEN and the risk of developing serious muscle problems (see Do not take CRESAGEN above).

Fusidic acid (an antibiotic) may increase the risk of developing serious muscle problems (see Take special care with CRESAGEN above). If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using CRESAGEN. Your doctor will tell you when it is safe to restart CRESAGEN. Taking CRESAGEN with fusidic acid may lead to muscle weakness, tenderness or pain (rhabdomyolysis).

Medicines used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see Take special care with CRESAGEN above), may increase the effect of CRESAGEN and may lead to an increase in the possible side effects of CRESAGEN: ritonavir, lopinavir, atazanavir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir, darunavir, tipranavir.

Effect of CRESAGEN may be increased with:

- Warfarin or clopidogrel (or any other medicine used for thinning the blood) as CRESAGEN may affect the way these medicine works; clopidogrel may increase the effect of CRESAGEN.

- Regorafenib (used to treat cancer) as this may increase the effect of CRESAGEN.
- Eltrombopag (used to treat low blood platelet counts caused by an autoimmune disorder) as this may increase the effect of CRESAGEN.
- Dronedarone (used to treat abnormal heart rhythm) as this may increase the effect of CRESAGEN.
- Itraconazole (used to treat fungal infections) as this may increase the effect of CRESAGEN.

Effect of CRESAGEN may be decreased:

- Indigestion remedies, such as antacids (used to neutralise acid in your stomach) as these medicines may decrease the effect of CRESAGEN.
- Erythromycin (an antibiotic) as this may decrease the effect of CRESAGEN.

CRESAGEN may increase the effect of other medicines:

- Oral contraceptives (the pill): CRESAGEN may increase the effect of contraceptives.
- Hormone replacement therapy: CRESAGEN may increase the effect of these medicines.

CRESAGEN with food and alcohol

You can take CRESAGEN with or without food. If you regularly drink large amounts of alcohol, it may increase your risk of muscle disorders.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Women of child-bearing potential should use appropriate contraceptive measures.

CRESAGEN is contraindicated in pregnancy and lactation.

Driving and using machines

CRESAGEN may cause dizziness, therefore you should not drive or use machines until you know how CRESAGEN affects you.

It is not always possible to predict to what extent CRESAGEN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CRESAGEN affects them.

CRESAGEN contains lactose

CRESAGEN tablets contain lactose monohydrate. If you have been told by your doctor that you have intolerance to some sugars (lactose or milk sugar), talk to your doctor before taking CRESAGEN tablets.

Do not stop your treatment without consulting your doctor.

3. How to take CRESAGEN

Do not share medicines prescribed for you with any other person.

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

Before starting treatment, your doctor should place you on a standard cholesterol-lowering diet that should continue during treatment.

The dosage range for CRESAGEN is 5 - 40 mg orally once a day. The recommended start dose is 5 mg once a day.

Your dosage will be individualised according to your cholesterol levels, your risk factors and your response to CRESAGEN-therapy. The majority of patients are controlled at the 10 mg dose. However, if necessary, dose adjustment can be made at 2 – 4 week intervals.

A 5 mg starting dose is recommended for patients of Asian ancestry and for patients requiring a smaller reduction in “bad” cholesterol (LDL-C) to achieve treatment target.

For patients with severely high cholesterol (including genetically inherited high cholesterol,), a start dose of 20 mg may be considered.

For patients with genetically inherited high cholesterol, a start dose of 20 mg once a day is recommended.

Children and adolescents 10 - 17 years of age:

In children and adolescents with genetically inherited high cholesterol, the usual dose range is 5 - 20 mg orally once daily.

Special populations:

Use in the elderly:

The usual dose range applies.

Dosage in patients with renal insufficiency:

The starting dose applies in patients with mild to moderate renal impairment.

For patients with severe renal impairment the dose of CRESAGEN should not exceed 10 mg once daily.

Dosage in patients with hepatic insufficiency:

The usual starting dose applies in patients with mild to moderate hepatic impairment. Patients with severe hepatic impairment should start therapy with CRESAGEN 5 mg, doses above 10 mg should be carefully considered.

Race:

A 5 mg starting dose of CRESAGEN should be considered for Asian patients.

Your doctor will tell you how long your treatment with CRESAGEN will last. It may take weeks or months of treatment for you to see any improvement in your symptoms and your symptoms might even worsen when CRESAGEN is started. Do not stop treatment early.

If you have the impression that the effect of CRESAGEN is too strong or too weak, tell your doctor or pharmacist.

If you take more CRESAGEN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take use CRESAGEN

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

CRESAGEN can have side effects.

Not all side effects reported for CRESAGEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CRESAGEN, please consult your health care provider for advice.

If any of the following happens, stop taking / using CRESAGEN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat which may cause difficulty in swallowing, severe itching ng of the skin (with raised lumps).
- Blistering of the skin, mouth and eyes (Steven-Johnson syndrome).
- Yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious reaction to CRESAGEN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you have any unusual aches or pains in your muscles which go on for longer than you might expect, especially if you develop a fever or feel unwell. These have become a potentially life-threatening muscle damage known as rhabdomyolysis. Muscle symptoms are more frequent in children and adolescents than in adults.
- Tendon disorders sometimes complicated by rupture.
- Serious muscle damage presenting as unexplained muscle aches and pains, feeling unwell and a fever (immune-mediated necrotising myopathy).
- Severe stomach pain due to inflamed pancreas (pancreatitis)
- Increase in liver enzymes in the blood.
- Hepatitis (an inflamed liver).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- Headache
- Dizziness
- Stomach pain
- Constipation
- Feeling sick (nausea)
- Muscle pain

- Feeling weak (asthenia)
- Increased blood glucose levels, diabetes

Less frequent

- Abnormal bleeding or bruising
- Rash, itching or other skin reactions
- Memory loss or impairment, forgetfulness and confusion
- Numbness, tingling, loss of sensation in the arms and legs, burning feeling in the hands or feet (polyneuropathy)
- Oedema (swelling under the skin)
- Cough, shortness of breath¸ difficulty breathing
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells)
- Muscle rupture
- A severe stomach pain (inflamed pancreas)
- Jaundice (yellowing of the skin and eyes)
- Hepatitis (an inflamed liver)
- Increased liver enzymes in the blood
- Joint pain
- Traces of blood in your urine
- Breast enlargement in men (gynaecomastia).

Side effects with unknown frequency:

- Depression
- Diarrhoea
- An increase in the amount of protein in the urine
- Numbness and tingling in hands or feet (peripheral neuropathy).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CRESAGEN.

5. How to store CRESAGEN

Store all medicines out of reach of children.

- Store at or below 30 °C
- Store in the original package/ container
- Protect from light / moisture
- Do not store in a bathroom
- Do not use after the expiry date stated on the carton

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CRESAGEN contains

- The active substance is rosuvastatin calcium

The other ingredients are:

Crospovidone type A

Lactose monohydrate

Hypromellose

Magnesium stearate

Microcrystalline cellulose type 102

Titatnium dioxide

Triacetin (E15178)

In addition:

CRESAGEN 5: Quinoline yellow aluminum lake (E104)

CRESAGEN 10: Allura red aluminum lake (E129)

CRESAGEN 20: Carmine (E120)

CRESAGEN 40: Sunset yellow aluminum lake (E 110) and Ponceau aluminum lake (E 124)

What CRESAGEN looks like and contents of the pack

CRESAGEN 5: Round, biconvex, yellow film-coated tablets, 6 mm in diameter, debossed with "5" on one side.

CRESAGEN 10: Round, biconvex, light pink film-coated tablets, 7 mm in diameter, debossed with "10" on one side.

CRESAGEN 20: Round, biconvex, dark pink film-coated tablets, 9 mm in diameter, debossed with "20" on one side.

CRESAGEN 40: Round, biconvex, red film-coated tablets, 10 mm in diameter, debossed with "40" on one side.

Holder of Certificate of Registration

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CRESAGEN 5 Tablets 44/7.5/1065

CRESAGEN 10 Tablets 44/7.5/1066

CRESAGEN 20 Tablets 44/7.5/1067

CRESAGEN 40 Tablets 44/7.5/1068

Access to the corresponding Professional Information

PI is avaiable in the carton or on our website