

CELMANTIN FILM COATED TABLET

Rosuvastatin (10mg, 20mg)

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What Celmantin is used for

Celmantin is prescribed to you because you have a high cholesterol level. This means you are at risk from a heart attack or stroke.

How Celmantin works

Celmantin 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).

- Celmantin can reduce the 'bad' cholesterol and increase the 'good' cholesterol.
- It works by helping to block 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 Celmantin, 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.

Before you use Celmantin

- When you must not use it

Do not take Celmantin if:

- You are allergic to rosuvastatin, or any of the other ingredients in this medicine.
- You have liver disease.
- If you have severe kidney problems.
- You have repeated or unexplained muscle aches or pains.
- You are taking ciclosporin, sofosbuvir, velpatasvir, voxilarevir
- If you are pregnant or breast-feeding. If you become pregnant while taking Celmantin, stop taking it immediately and tell your doctor.

If any of the above applies to you, do not take the tablets. Consult your doctor and take his/her advice.

Pregnancy and breastfeeding

Do not take Celmantin if you are pregnant or breast-feeding. If you become pregnant while taking Celmantin stop taking it immediately and tell your doctor.

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

- Before you start to use it

Talk to your doctor or pharmacist before taking Celmantin:

- If you have problems with your kidneys.
- 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.
- If you have problems with your liver.
- If your thyroid gland is not working properly.
- If you regularly drink large amounts of alcohol.
- If you are over 70
- If you take other medicines called fibrates to lower your cholesterol.
- 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 Celmantin can lead to serious muscle problems (rhabdomyolysis).

- If you take medicines used to fight the HIV infection (e.g. lopinavir/ritonavir).
- If you have severe respiratory failure.
- If you have diabetes.
- If you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken 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)
- antacid (used to neutralise acid in your stomach)
- erythromycin (an antibiotic)
- Lopinavir/ritonavir (used to fight HIV infection)

How to use Celmantin

- How much to use

Starting dose:

In adults treatment with Celmantin is usually started with the 10mg dose taken once daily, even if you have taken a higher dose of a different statin before. Some people may be asked to start treatment with one 5mg tablet taken once a day. 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 may be more sensitive to possible side effects.

Increasing the dose and maximum daily dose:

After checking the amount of lipids in your blood, your doctor may decide to increase your dose until you are taking the amount of Celmantin that is right for you. There will be a gap of four weeks between every dose adjustment.

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In adults the maximum daily dose of Celmantin is 40mg. It is only for patients with high cholesterol levels and at high risk of heart attack or stroke whose cholesterol levels are not lowered enough with 20mg. A dosage of 40mg once daily should only be initiated under specialist supervision.

In children 10-17 years of age the maximum daily dose is 20mg. Celmantin should not be given to children younger than 10 years.

- When to use it

Take Celmantin once daily. You can either take it in the morning or evening. Always take Celmantin exactly as your doctor has told you. Try to take your tablet at the same time every day to help you to remember to take 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 Celmantin that is right for you.

- How long to use it

Do not stop taking Celmantin even if you are feeling well, unless your doctor tells you to or unless you become pregnant. Talk to your doctor if you want to stop taking Celmantin. Your cholesterol levels might increase again if you stop taking Celmantin.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If you take more Celmantin than prescribed by your doctor, contact your doctor or pharmacist immediately.

While you are using it

- Things you must do

Take our medication daily as prescribed. 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.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not give Celmantin to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Driving and using machines

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

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Celmantin 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 Celmantin 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. 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.

If you have muscle problems that do not go away even after your doctor has told you to stop taking Celmantin, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

Common (affects more than 1 in 10 patients) side effects:

- Headache and dizziness
- Stomach pain
- Constipation
- General feeling of weakness
- Muscle pain
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your Celmantin tablets (only Celmantin 40 mg).

Uncommon (affects more than 1 in 100 patients) side effects:

- Skin rash
- Itching
- Hives
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your Celmantin tablets (only Celmantin 10mg and 20mg).

Rare (affects more than 1 in 1000 patients) side effects:

- 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 Celmantin and seek medical help immediately.
- Muscle damage in adults – as a precaution, stop taking Celmantin 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 (affects less than 1 in 10,000) side effects:

- Jaundice (yellowing of the skin and eyes)
- Hepatitis (an inflamed liver)
- Joint pain
- Memory loss

Side effects of not known frequency may include:

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- Sleep disturbances, including insomnia (difficulty in sleeping) and nightmares
- Depression
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness).

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

Traces of blood in your urine (generally temporary and not associated with worsening kidney function). Increases in HbA1c (a measure of the average amount of sugar in your blood over time). 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring or by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Celmantin

- Storage

Keep out of the reach and sight of children.

Stored below 30°C in original pack in order to protect from light.

- Disposal

Do not use the medicine after the expiry date printed on the pack. The expiry date refers to the last day of that month.

Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Celmantin 10mg film coated tablet is pink, round, biconvex, coated tablet,

embossed ROS over 10 on one side and nothing on the other, with diameter 7mm. Celmantin 20mg film coated tablet is pink, round, biconvex, coated tablet, embossed ROS over 20 on one side and nothing on the other, with diameter 9mm.

- Ingredients

Active ingredient (s)

Celmantin 10mg Film Coated Tablet contains 10mg rosuvastatin

Celmantin 20mg Film Coated Tablet contains 20mg rosuvastatin

Inactive ingredients

The other ingredients are: Cellulose Microcrystalline PH-101, Silica Colloidal Anhydrous, Crospovidone Type A, Cellulose Microcrystalline PH-102, Lactose Monohydrate, Magnesium Stearate.

The tablet coating contains: Opadry II Pink 33K94423

The tablets are packed in Alu-Alu blisters with pack sizes of 30, 100 and 500.

- MAL number

Celmantin	10mg	Tablet
MAL23076012AZ		
Celmantin	20mg	Tablet
MAL23076013AZ		

Manufacturer

Medochemie Ltd (Central Factory),
1-10, Constantinoupolis Street, 3011
Limassol, Cyprus

Product Registration Holder

Komedic Sdn Bhd,
4 Jalan PJS 11/14, Bandar Sunway,
46150 Petaling Jaya, Selangor D.E.

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