Package leaflet: Information for the user

CELMANTIN 5 mg film-coated tablets

CELMANTIN 10 mg film-coated tablets

CELMANTIN 20 mg film-coated tablets

CELMANTIN 40 mg film-coated tablets

Rosuvastatin

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. See section 4.

What is in this leaflet

1. What CELMANTIN is and what it is used for
2. What you need to know before you take CELMANTIN
3. How to take CELMANTIN
4. Possible side effects
5. How to store CELMANTIN
6. Contents of the pack and other information

1. What CELMANTIN is and what it is used for

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

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

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 buildup of fatty deposits in your arteries.

Why is it important to keep taking CELMANTIN?

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 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 CELMANTIN**, even if it has got your cholesterol to the right level, because **it prevents your cholesterol levels from creeping up again** and causing buildup of fatty deposits. However, you should stop if your doctor tells you to do so, or you have become pregnant.

2. What you need to know before you take CELMANTIN

Do not take CELMANTIN:

- **If you are allergic to rosuvastatin**, or any of the other ingredients of this medicine (listed in section 6).
- **If you are pregnant** or breast-feeding. If you become pregnant while taking CELMANTIN **stop taking it immediately and tell your doctor**. Women should avoid becoming pregnant while taking CELMANTIN 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 combination of sofosbuvir/ velpatasvir/ voxilaprevir** (used for viral infection of the liver called hepatitis C).
- **If you take a drug called ciclosporin** (used, for example, after organ transplants)
- **If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores** after taking rosuvastatin or other related medicines.

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 CELMANTIN 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**.

Warnings and precautions

Talk to your doctor or pharmacist before taking CELMANTIN:

- **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 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 or lead to the occurrence of myasthenia (see section 4).
- **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 CELMANTIN**".
- **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 PRODUCT can lead to serious muscle problems (rhabdomyolysis).
- **If you are over 70** (as your doctor needs to choose the right start dose of CELMANTIN 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 CELMANTIN to suit you.

Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with rosuvastatin treatment. Stop using rosuvastatin and seek medical attention immediately if you notice any of the symptoms described in section 4.

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

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

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 CELMANTIN. 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.

Children and adolescents

- **If the patient is under 6 years old**: CELMANTIN should not be given to children younger than 6 years.
- **If the patient is below 18 years of age**: The CELMANTIN 40 mg tablet is not suitable for use in children and adolescents below 18 years of age.

Other medicines and CELMANTIN

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, ticagrelor 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 below and Warnings and precautions),
- an oral contraceptive (the pill),
- regorafenib (used to treat cancer),
- darolutamide (used to treat cancer),
- hormone replacement therapy,

- any of the following drugs used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see Warnings and precautions): ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.

The effects of these medicines could be changed by CELMANTIN or they could change the effects of CELMANTIN.

If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart CELMANTIN. Taking CELMANTIN with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

CELMANTIN with food and drink

You can take CELMANTIN with or without food.

Pregnancy and breast-feeding

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. Women should avoid becoming pregnant while taking CELMANTIN 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 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.

CELMANTIN contains lactose monohydrate.

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

For a full list of ingredients please see Section 6 "**Contents of the pack and other information**".

3. How to take CELMANTIN

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

The recommended dose in adults is:

If you are taking CELMANTIN for high cholesterol:

Starting dose

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

Taking your tablets

Swallow each tablet whole with a drink of water.

Take CELMANTIN 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 CELMANTIN that is right for you.

If you take more CELMANTIN 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 CELMANTIN.

If you forget to take CELMANTIN

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 CELMANTIN

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

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 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).
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

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. 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*.
- If you experience muscle rupture.
- If you have lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

Common possible side effects (may affect up to 1 in 10 people):

- 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 CELMANTIN tablets (only CELMANTIN 40 mg).
- 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 (may affect up to 1 in 100 people):

- 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 CELMANTIN tablets (only CELMANTIN 5 mg, 10 mg and 20 mg).

Rare possible side effects (may affect up to 1 in 1,000 people):

- 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.
- Bleeding or bruising more easily than normal due to low level of blood platelets.
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

Very rare possible side effects (may affect up to 1 in 10,000 people):

- 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 not known frequency may include:

- Diarrhoea (loose stools), 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.
- 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.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects via the national reporting system: ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store CELMANTIN

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 carton and blister after "EXP". The expiry date refers to the last day of that month.
This medicinal Celmantin does not require any special temperature storage conditions. Store in the original package in order to protect from light.
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.

6. Contents of the pack and other information

What CELMANTIN contains

- The active substance is rosuvastatin.
  Each film-coated tablet contains 5 mg, 10 mg, 20 mg or 40 mg rosuvastatin as rosuvastatin calcium, respectively.
- 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:

CELMANTIN 5 mg film-coated tablets: Hypromellose, Titanium dioxide (E171), Lactose monohydrate, Triacetin, Iron oxide yellow (E172).

CELMANTIN 10 mg film-coated tablets: Hypromellose, Titanium dioxide (E171), Lactose monohydrate, Triacetin, Iron oxide red (E172).

CELMANTIN 20 mg film-coated tablets: Hypromellose, Titanium dioxide (E171), Lactose monohydrate, Triacetin, Iron oxide red (E172).

CELMANTIN 40 mg film-coated tablets: Hypromellose, Titanium dioxide (E171), Lactose monohydrate, Triacetin, Iron oxide red (E172).

What CELMANTIN looks like and contents of the pack

CELMANTIN 5 mg film-coated tablets: Yellow, round, biconvex, coated tablet, embossed 'ROS' over '5' on one side and nothing on the other, with diameter 7 mm.

CELMANTIN 10 mg film-coated tablets: Pink, round, biconvex, coated tablet, embossed 'ROS' over '10' on one side and nothing on the other, with diameter 7 mm.

CELMANTIN 20 mg film-coated tablets: Pink, round, biconvex, coated tablet, embossed 'ROS' over '20' on one side and nothing on the other, with diameter 9 mm.

CELMANTIN 40 mg film-coated tablets: Pink, oval, biconvex, coated tablet, embossed 'ROS' on one side and '40' on the other side, with dimensions 6.8 x 11.4 mm.

Tablets are packed in OPA-Al-PVC/Al blisters.

Boxes containing 14, 20, 28, 30, 56, 60, 84, 90 and 100 film-coated tablets in blisters are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Medochemie Ltd- Central Factory 1-10 Constantinoupoleos Str., Limassol,
3011, Cyprus.

&

Medochemie Ltd- Factory AZ
2 Michael Erakleous Str.,
Ag. Athanassios Industrial Area, 4101 Ag. Athanassios, Limassol, Cyprus

Marketing Authorization Holder

Medochemie Ltd.
1-10 Constantinoupoleos Street
Limassol
3011
Cyprus

For any information about this medicine, please contact the Marketing Authorization Holder.

This medicinal Celmantin is authorized in the Member States of the EEA under the following names:

	2231	**2232**
Denmark	Celmantin 5, 10, 20, 40 mg film coated tablets	Rovasyn 5, 10, 20, 40 mg film coated tablets
Bulgaria	Rovasta 10, 20 mg film coated tablets	
Cyprus	Celmantin 5, 10, 20, 40 mg Δισκία επικαλυμμένα με υμένιο	Rovasyn 5, 10, 20, 40 mg film coated tablets Δισκία επικαλυμμένα με υμένιο
Czech Republic	ROVASYN 10, 20, 40 mg potahované tablety	
Estonia	RovasYN 10, 20 mg Õhukese polümeerikattega tabletid	
Greece	Celmantin 5, 10, 20, 40 mg film coated tablets	
Latvia	RovasYN 5, 10, 20, 40 mg apvalkotās tabletes	
Romania	Rovastamed 5, 10, 20, 40 mg comprimate filmate	
Malta	Celmantin 5, 10, 20, 40 mg film coated tablets	

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