

Package leaflet: Information for the user

Rosuvastatin TAD 5 mg film-coated tablets
Rosuvastatin TAD 10 mg film-coated tablets
Rosuvastatin TAD 15 mg film-coated tablets
Rosuvastatin TAD 20 mg film-coated tablets
Rosuvastatin TAD 30 mg film-coated tablets
Rosuvastatin TAD 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 Rosuvastatin TAD is and what it is used for
2. What you need to know before you take Rosuvastatin TAD
3. How to take Rosuvastatin TAD
4. Possible side effects
5. How to store Rosuvastatin TAD
6. Contents of the pack and other information

1. What Rosuvastatin TAD is and what it is used for

Rosuvastatin TAD belongs to a group of medicines called statins.

You have been prescribed Rosuvastatin TAD because:

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

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 is it important to keep taking Rosuvastatin TAD?

Rosuvastatin TAD 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 TAD 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 TAD**, 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. What you need to know before you take Rosuvastatin TAD

Do not take Rosuvastatin TAD:

- 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 Rosuvastatin TAD **stop taking it immediately and tell your doctor**. Women should avoid becoming pregnant while taking Rosuvastatin TAD 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 TAD 30 mg or 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 Rosuvastatin TAD

- 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. ritonavir with lopinavir and/or atazanavir, please see Taking other medicines.

- If the patient is under 6 years old: Rosuvastatin TAD should not be given to children younger than 6 years.
- If the patient is below 18 years of age: The Rosuvastatin TAD 30 mg and 40 mg tablets are 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 TAD 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 TAD to suit you.
- 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 <Invented name> can lead to serious muscle problems (rhabdomyolysis).

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

- **Do not take Rosuvastatin TAD 30 mg and 40 mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of Rosuvastatin TAD.**

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 TAD**.

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.

Other medicines and Rosuvastatin TAD

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,
- 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 Rosuvastatin TAD. Taking Rosuvastatin TAD with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4,
- regorafenib (used to treat cancer),
- 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, simeprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.

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

Rosuvastatin TAD with food and drink

You can take Rosuvastatin TAD with or without food.

Pregnancy and breast-feeding

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

Rosuvastatin TAD contains lactose (a type of sugar)

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

3. How to take Rosuvastatin TAD

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

Usual doses in adults

If you are taking Rosuvastatin TAD for high cholesterol:

Starting dose

Your treatment with Rosuvastatin TAD 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.

Not all Rosuvastatin TAD tablet strengths may be available.

Please check with your doctor or pharmacist which start dose of Rosuvastatin TAD 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

In order to reach adequate cholesterol levels, your doctor may decide to gradually increase your dose up to a maximum dose of a 40 mg tablet once daily. There will be a gap of four weeks between every dose adjustment.

The maximum daily dose of Rosuvastatin TAD 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 lower doses.

If you are taking Rosuvastatin TAD 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 dose range in children and adolescents aged 6 to 17 years is 5 to 20 mg once daily. The usual start dose is 5 mg per day and your doctor may gradually increase your dose to find the right amount of Rosuvastatin TAD for you. The maximum daily dose of Rosuvastatin TAD is 10 or 20 mg for children

aged 6 to 17 years depending on your underlying condition being treated. Take your dose once a day. Rosuvastatin TAD 30 mg or 40 mg tablets should not be used by children.

Taking your tablets

Swallow each tablet whole with a drink of water.

Take Rosuvastatin TAD 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 TAD that is right for you.

If you take more Rosuvastatin TAD 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 TAD.

If you forget to take Rosuvastatin TAD

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 have missed.

If you stop taking Rosuvastatin TAD

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

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 Rosuvastatin TAD and seek medical help immediately if you have any of the following side effects:

- 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 TAD and talk to your doctor immediately if you have any of the following:

- 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.
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).
- Muscle rupture.

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 TAD tablets (only the 40 mg dose).
- 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 (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 TAD tablets (only doses 5–20 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 TAD** and seek medical help immediately
- Muscle damage in adults – as a precaution, **stop taking Rosuvastatin TAD 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.
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

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
- Gynecomastia (breast enlargement in men)

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
- Tendon injury
- Muscle weakness that is constant.

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 directly via www.ravimiamet.ee . By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rosuvastatin TAD

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 packaging after EXP. The expiry date refers to the last day of that month.

This medicinal product 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 Rosuvastatin TAD contains

- The active substance is rosuvastatin.
Each film-coated tablet contains 5 mg rosuvastatin (as rosuvastatin calcium).
Each film-coated tablet contains 10 mg rosuvastatin (as rosuvastatin calcium).
Each film-coated tablet contains 15 mg rosuvastatin (as rosuvastatin calcium).
Each film-coated tablet contains 20 mg rosuvastatin (as rosuvastatin calcium).
Each film-coated tablet contains 30 mg rosuvastatin (as rosuvastatin calcium).
Each film-coated tablet contains 40 mg rosuvastatin (as rosuvastatin calcium).
- The other ingredients are lactose, microcrystalline cellulose, crospovidone, magnesium stearate and colloidal anhydrous silica in the tablet core and lactose monohydrate, titanium dioxide (E171), macrogol 6000 and basic butylated methacrylate copolymer in the film coating.

What Rosuvastatin TAD looks like and contents of the pack

Rosuvastatin TAD 5 mg film-coated tablets are white, round (diameter 7 mm), slightly biconvex, film-coated tablets with bevelled edges and with engraved number 5 on one side.

Rosuvastatin TAD 10 mg film-coated tablets are white, round (diameter 7.5 mm), slightly biconvex, film-coated tablets with bevelled edges and with engraved number 10 on one side.

Rosuvastatin TAD 15 mg film-coated tablets are white, round (diameter 9 mm), slightly biconvex, film-coated tablets with bevelled edges and with engraved number 15 on one side.

Rosuvastatin TAD 20 mg film-coated tablets are white, round (diameter 10 mm), film-coated tablets with bevelled edges.

Rosuvastatin TAD 30 mg film-coated tablets are white, biconvex, capsule-shaped film-coated tablets and with a score on both sides (dimensions 15 mm x 8 mm). The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Rosuvastatin TAD 40 mg film-coated tablets are white, biconvex, capsule-shaped film-coated tablets (dimensions 16 mm x 8.5 mm).

Boxes of 10, 14, 20, 28, 30, 56, 60, 84, 90, 98 and 100 film-coated tablets in blisters are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

TAD Pharma GmbH
Heinz-Lohmann-Straße 5
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Manufacturer

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