

Package leaflet: Information for the patient

RosstAacy 5 mg/100 mg capsules, hard
RosstAacy 10 mg/100 mg capsules, hard
RosstAacy 20 mg/100 mg capsules, hard

rosuvastatin/acetylsalicylic acid

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

1. What RosstAacy is and what it is used for

RosstAacy contains two active substances – rosuvastatin and acetylsalicylic acid.

- Rosuvastatin belongs to a group of substances called statins, which are lipid (fat) regulating medicines that are used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. Cholesterol is a fatty substance (lipid) that can cause the narrowing of blood vessels in the heart causing coronary heart disease. If you are at risk of another heart attack, rosuvastatin can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.
- Acetylsalicylic acid in low doses belongs to a group of medicines called anti-platelet agents. Platelets are tiny cells in the blood that cause the blood to clot and are involved in thrombosis. When a blood clot occurs in an artery it stops the blood flowing and cuts off the oxygen supply. When this happens in the heart it can cause a heart attack or angina.

These two active substances, taken together, reduce the chance of having another heart attack if you have previously had a heart attack or if you suffer from chest pain attacks (unstable angina pectoris). RosstAacy is indicated in patients who are already taking rosuvastatin and acetylsalicylic acid at these doses. Instead of taking rosuvastatin and acetylsalicylic acid separately you will receive one capsule of RosstAacy which contains both ingredients in the same strength as before.

2. What you need to know before you take RosstAacy

Do not take RosstAacy:

- If you are allergic to rosuvastatin, acetylsalicylic acid, to any other salicylates or non-steroidal anti-inflammatory drugs (NSAIDs) or any of the other ingredients of this medicine (listed in section 6).

- If you are allergic to peanut or soya (see below).
- If you are pregnant or breast-feeding or if you become pregnant while taking RosstAacy stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking RosstAacy 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 had an asthma attack or swelling of some parts of the body e.g. face, lips, throat or tongue (angioedema) after taking salicylates or NSAIDs.
- If you currently have or have ever had an ulcer in your stomach or small intestine or any other type of bleeding like a stroke.
- If you have ever had the problem of your blood not clotting properly.
- If you suffer from gout.
- If you suffer from uncompensated heart failure.
- If you are taking a medicine called methotrexate (e.g. for cancer or rheumatoid arthritis) in doses higher than 15 mg per week.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking the medicine or other similar medicines.

Warnings and precautions

Talk to your doctor or pharmacist before taking RosstAacy

- 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 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 against the HIV infection e.g. ritonavir with lopinavir and/or atazanavir, please see “Other medicines and RosstAacy”.
- If you are taking or have taken in the last 7 days medicine containing fusidic acid (used to treat bacterial infections) administered orally or by injection; taking RosstAacy with fusidic acid can lead to severe ailments of the muscles (rhabdomyolysis); please see “Other medicines and RosstAacy”.
- If you have severe respiratory failure.
- If you are over 70.
- 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 RosstAacy to suit you.
- If you have or have ever had problems with your stomach or small intestine (ulcers, or gastrointestinal bleeding).
- If you have high blood pressure.
- If you are asthmatic, have hay fever, nasal polyps or other chronic respiratory diseases; acetylsalicylic acid may induce an asthma attack.
- In case of hypersensitivity (allergy) to other pain and anti-inflammatory medicines, other medicines for rheumatism or other allergy-causing factors.
- If there are other allergies (e.g. with skin reactions, itching).
- If you take other medicines called anticoagulants (e.g. coumarin derivatives, heparin – with the exception of low-dose heparin treatment).
- With impaired kidney function or reduced cardiac and vascular blood flow (e.g. vascular disease of the kidneys, cardiac muscle weakness, reduced blood volume, major operations,

- blood poisoning or increased bleeding): acetylsalicylic acid can further increase the risk of renal dysfunction and acute kidney failure.
- If you have heavy menstrual periods.

You must immediately seek medical advice, if your symptoms get worse or if you experience severe or unexpected side effects e.g. unusual bleeding symptoms, serious skin reactions or any other sign of serious allergy (see section “Possible side effects”).

Metamizole (substance to decrease pain and fever) may reduce the effect of acetylsalicylic acid on platelet aggregation (blood cells sticking together and forming a blood clot), when taken concomitantly. Therefore, this combination should be used with caution in patients taking low dose aspirin for cardioprotection.

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 RosstAacy.

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.

You should take care not to become dehydrated (you may feel thirsty with a dry mouth) since the use of acetylsalicylic acid at the same time may result in deterioration of kidney function.

Inform your doctor if you are planning to have an operation (even a minor one, such as tooth extraction) since acetylsalicylic acid is blood-thinning there may be an increased risk of bleeding.

Acetylsalicylic acid may cause Reye’s syndrome when given to children. Reye’s syndrome is a very rare disease which affects the brain and liver and can be life threatening. For this reason, RosstAacy should not be given to children and adolescents aged under 18 years.

In patients with severe glucose-6-phosphate dehydrogenase deficiency: acetylsalicylic acid can cause an accelerated breakdown or breakdown of red blood cells or a certain form of anemia. This risk can be caused by factors such as high dosage, fever or acute infections may be increased.

Acetylsalicylic acid reduces uric acid excretion in low doses. This can trigger a gout attack in patients at risk.

If you cut or injure yourself, it may take a little longer than usual for bleeding to stop. This is related to the effect of acetylsalicylic acid. Small cuts and injuries (e.g. when shaving) are usually of no importance. If you have unusual bleeding (in an unusual place or of unusual duration), contact your doctor.

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

Children and adolescents

RosstAacy should not be used in children and adolescents.

Other medicines and RosstAacy

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

RosstAacy may affect or be affected by other medicines, such as:

- 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);
- an oral contraceptive (the pill);
- hormone replacement therapy;
- regorafenib (used to treat cancer);
- darolutamide (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, sofosbuvir, voxilaprevir, simeprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir;
- ketoconazole, itraconazole (anti-fungal medicines);
- rifampicin, erythromycin, clarithromycin (antibiotics);
- thinning of the blood/prevention of clots (e.g. warfarin, heparin, coumarin, clopidogrel, ticlopidine): acetylsalicylic acid may increase the risk of bleeding if taken before blood clot-removing or thinning of the blood treatment. Therefore, if you are to undergo such treatment, you should pay attention to signs of external or internal bleeding (e.g. bruises);
- rejection of organ after transplantation (ciclosporin, tacrolimus);
- high blood pressure (e.g. diuretics and ACE-inhibitors);
- regulation of the heart beat (digoxin);
- manic-depressive illness (lithium);
- pain and inflammation (e.g. NSAIDs such as ibuprofen, naproxen or steroids);
- gout (e.g. probenecid, benzbromarone);
- glaucoma (acetazolamide);
- cancer or rheumatoid arthritis (methotrexate; in doses lower than 15 mg per week);
- blood sugar lowering drugs (antidiabetic drugs) (e.g. glibenclamide) – the blood sugar level may drop;
- depression (selective serotonin re-uptake inhibitors (SSRIs) such as sertraline or paroxetine);
- use as hormone replacement therapy when the adrenal glands or pituitary gland have been destroyed or removed (with the exception of products that are applied on the skin or in cortisone replacement therapy for Addison’s disease), or to treat inflammation, including rheumatic diseases and inflammation of the intestines (corticosteroids). Concomitant use increases the risk of gastrointestinal side effects;
- seizures of the brain – epilepsy (valproic acid);
- drugs that cause increased urinary excretion (diuretics: so-called aldosterone antagonists such as spironolactone and canrenoate, loop diuretics, e.g. furosemide);
- Alcohol: the risk of gastrointestinal ulcers and bleeding is increased.

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

RosstAacy with food and drink

Drinking alcohol may possibly increase the risk of gastrointestinal bleeding and prolong bleeding time.

Pregnancy and breast-feeding

Do not take RosstAacy if you are pregnant or breast-feeding. If you become pregnant while taking RosstAacy stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking RosstAacy by using suitable contraception.

Driving and using machines

Most people can drive a car and operate machinery while using RosstAacy – it will not affect their ability. However, some people feel dizzy during treatment with RosstAacy. If the capsules make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

RosstAacy contains lactose

If you have been told by your doctor that you have an intolerance to some sugars (lactose or milk sugar), contact your doctor before taking RosstAacy.

RosstAacy contains soya oil.

If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take RosstAacy

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

Adults

Your doctor will determine the appropriate strength for you, depending on your condition, your current treatment and your personal risk status.

This medicine is not suitable to start a treatment. Treatment initiation should only be done by giving the active substances separately and after setting the appropriate doses the switch to RosstAacy of the appropriate strength is possible.

The recommended dose is one capsule per day.

This medicine should be taken with food. You should take your medicine at the same time each day. Capsules should be swallowed with plenty of liquid and should not be crushed or chewed.

If you go into hospital or receive treatment for another condition, tell the medical staff that you're taking RosstAacy.

Use in elderly patients

There is no need to modify the dose for elderly patients

Use in children and adolescents

RosstAacy should not be used in children and adolescents.

Patients with kidney impairment

Dose change is not necessary if you suffer from mild or moderate kidney impairment

The use of RosstAacy in patients with severe kidney impairment is contraindicated.

Patients with liver impairment

Dose change is not necessary if you suffer from mild or moderate liver impairment.

The use of RosstAacy in patients with severe liver impairment is contraindicated.

If you take more RosstAacy than you should

Contact your doctor or nearest hospital for advice.

If you forget to take RosstAacy

Do not worry. If you forget to take a capsule, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a forgotten capsule.

If you stop taking RosstAacy

Your doctor will advise you how long to take your medicine. Your cholesterol levels might increase again if you stop taking RosstAacy. Your condition may return if you stop using your medicine before you are advised.

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.

Stop taking RosstAacy and seek medical help **immediately** if you experience any of the following very rare, severe side effects after taking this medicine;

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing;
- Swelling of eyelids, face or lips;
- Swelling of the tongue and throat which causes great difficulty breathing and/or swallowing;
- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens-Johnson Syndrome) or other allergic reactions;
- If you experience black stools or vomiting with blood (signs of heavy bleeding from the stomach);
- 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 RosstAacy 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 experience muscle rupture;**
- **If you have lupus-like disease syndrome** (including rash, joint disorders and effects on blood cells).

The following **side-effects** have been reported. If any of these cause you problems or if they **last for more than one week**, you should **contact your doctor**.

ROSUVASTATIN

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

- Headache;
- Stomach pain;
- Constipation;
- Feeling sick;
- Muscle pain;
- Feeling weak;
- Dizziness;
- 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 (may affect up to 1 in 100 people):

- Rash, itching, hives 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 RosstAacy capsules (only doses 5–20 mg).

Rare (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 RosstAacy and seek medical help immediately;**
- Muscle damage in adults – as a precaution, **stop taking RosstAacy 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;
- Reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia);
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

Very rare (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;
- Gynecomastia (breast enlargement in men);

Not known (frequency cannot be estimated from the available data):

- 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;
- A disorder of the nerves which can cause weakness, tingling or numbness;
- Muscle weakness that is constant.

ACETYLSALICYLIC ACID

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

- Gastrointestinal complaints such as heartburn, nausea, vomiting, abdominal pain and diarrhoea.
- Minor blood loss from gastrointestinal tract (micro-bleeding);
- Bleeding such as nosebleeds, bleeding gums, bleeding skin or bleeding the urinary tract and genital organs with a possible extension of the bleeding time. This effect can last for 4 to 8 days after ingestion.

Uncommon (may affect up to 1 in 100 people):

- Bleeding from the stomach or intestines. After long-term use of acetylsalicylic acid, anaemia (iron deficiency anaemia) can occur due to hidden blood loss from the stomach or intestines;
- Intracranial bleeding, blood in urine;
- Stomach or intestinal ulcers, which very rarely can lead to perforation;
- Gastrointestinal inflammation;
- Skin reactions.

Rare (may affect up to 1 in 1 000 people):

- Hypersensitivity reactions of the skin, the respiratory tract, the gastrointestinal area and the cardiovascular system, especially in asthmatics. The following disease features can occur: drop in blood pressure, attacks of breathlessness, inflammation of the nasal mucosa, nasal congestion, allergic shock, swelling of the face, tongue and larynx (Quincke's oedema);
- Serious bleeding such as bleeding from the brain, especially in patients with uncontrolled high blood pressure and / or concomitant treatment with anticoagulants (anticoagulant medicinal products), which may be life-threatening in individual cases;
- Confusion;
- Headache, dizziness;
- Impaired hearing or ringing in the ears (tinnitus), especially in children and the elderly, may be signs of an overdose (see also section "If you take more RosstAacy than you should");

Very rare (may affect up to 1 in 10 000 people):

- Increases in liver function tests;
- Renal dysfunction and acute kidney failure;
- Decrease in blood sugar (hypoglycemia);
- Acetylsalicylic acid reduces uric acid excretion in low doses. This may trigger a gout attack in patients at risk;
- Febrile rashes with mucous membrane involvement (erythema exudative multiforme).

Not known (frequency cannot be estimated from the available data):

- Accelerated degradation or decay of red blood cells and a specific form of blood poverty in patients with severe glucose-6-phosphate dehydrogenase deficiency.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 national reporting system:

Bulgarian Drug Agency
8 Damyan Gruev Str., 1303 Sofia
Tel.: +359 2 8903417
website: www.bda.bg

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store RosstAacy

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.

Store below 30°C. Store in the original package in order to protect from moisture.

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 RosstAacy contains

The active substances are rosuvastatin (as rosuvastatin calcium) and acetylsalicylic acid.

RosstAacy 5 mg/100 mg: each hard capsule contains 5 mg rosuvastatin (as rosuvastatin calcium) and 100 mg acetylsalicylic acid.

RosstAacy 10 mg/100 mg: each hard capsule contains 10 mg rosuvastatin (as rosuvastatin calcium) and 100 mg acetylsalicylic acid.

RosstAacy 20 mg/100 mg: each hard capsule contains 20 mg rosuvastatin (as rosuvastatin calcium) and 100 mg acetylsalicylic acid.

The other ingredients are:

*Film-coated tablet with **rosuvastatin**:*

Tablet core: Lactose monohydrate; cellulose, microcrystalline; magnesium oxide, heavy; crospovidone (type A); silica, colloidal anhydrous; magnesium stearate.

Film coating system: Polyvinyl alcohol; titanium dioxide (E 171); talc; iron oxide yellow (E 172);

lecithin (soya); iron oxide red (E 172); xanthan gum; black iron oxide (E 172).

*Tablet with **acetylsalicylic acid***: Cellulose, microcrystalline; maize starch; silica, colloidal anhydrous; stearic acid.

Capsule shell: Gelatin; titanium dioxide (E 171); indigotine (E 132); yellow iron oxide (E 172)

Black ink: shellac; propylene glycol; strong ammonia solution; black iron oxide (E 172); potassium hydroxide.

What RosstAacy looks like and contents of the pack

RosstAacy 5 mg/100 mg: hard gelatin capsules of size 2 and white opaque body and dark green opaque cap. Each capsule contains one white or almost white, biconvex, oval uncoated tablet of acetylsalicylic acid and one film-coated, brown, biconvex, round tablet of rosuvastatin 5mg

RosstAacy 10 mg/100 mg: hard gelatin capsules of size 1 and white opaque body with black overprint “ASA 100” and light green opaque cap with black overprint “RSV 10”. Each capsule contains one white or almost white, biconvex, oval uncoated tablet of acetylsalicylic acid and one film-coated, brown, biconvex, round tablet of rosuvastatin 10mg

RosstAacy 20 mg/100 mg: hard gelatin capsules of size 0 and white opaque body with black overprint “ASA 100” and green opaque cap with black overprint “RSV 20”. Each capsule contains one white or almost white, biconvex, oval uncoated tablet of acetylsalicylic acid and two film-coated, brown, biconvex, round tablets of rosuvastatin 10mg

RosstAacy is available in PA/Al/PVC (laminated) and aluminium lidding foil blisters containing 1, 10, 14, 28, 30, 56, 60, 84, 90, 168, 180 capsules, hard.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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