

Package leaflet: Information for the user

Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnii 5 mg/1000 mg, zachte capsules

rosuvastatin/omega-3-acid ethyl esters 90

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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3. How to take Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnii
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1. What Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnii is and what it is used for

Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnii contains the active ingredients rosuvastatin and omega-3-acid ethyl esters 90. Rosuvastatin belongs to a group of medicines called statins. Omega-3-acid ethyl esters 90 belong to a group of so called reducers of cholesterol and triglycerides.

You have been prescribed Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnii for the treatment of high cholesterol and triglyceride levels in your blood.

If you have high cholesterol and triglyceride levels, it means you are at risk from a heart attack or stroke. You have been advised to take Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnii, because changing your diet and taking more exercise were not enough to correct your cholesterol and triglyceride levels. You should continue with your cholesterol-lowering diet and exercise while you are taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnii.

Why it is important to keep taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnii

For most people, high cholesterol and triglycerides 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 and triglyceride levels, you can reduce your risk of having a heart attack, a stroke or related health problems.

You need to keep taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnii, even if it has got your cholesterol and triglycerides to the right level, because **it prevents them from creeping up again**. 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 Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil

Do not take Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil:

- If you are allergic to rosuvastatin, omega-3-acid ethyl esters 90, soy, or any of the other ingredients of this medicine (listed in section 6). Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil may contain traces of soybean oil.
- If you are pregnant or breast-feeding. If you become pregnant while taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil, stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil by using suitable contraception.
- If you have a 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 you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil or other related medicines.

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 Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil:

- 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 have, or have had, heart problems
- If you develop light-headedness, asthenia (feeling of weakness), palpitations or shortness of breath as these may be symptoms of an irregular and often very rapid heart rhythm (atrial fibrillation)
- 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. Read this leaflet carefully, even if you have taken other medicines for high cholesterol before.
- If you take medicines used to fight HIV infection, e.g. ritonavir with lopinavir and /or atazanavir, see “Other medicines and Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil”.
- 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 Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil can lead to serious muscle problems (*rhabdomyolysis*).
- If you are over 70
- If you have severe respiratory failure.
- If you are of Asian origin – that is Japanese, Chinese, Filipino, Vietnamese, Korean and Indian.
- If you are due to have or have had surgery recently.
- If you have had a trauma recently.
- If you have diabetes which is not controlled.
- If you are allergic to fish.

Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil treatment. Stop using Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil and seek medical attention immediately if you notice any of the symptoms described in section 4.

Children and adolescents

Children and adolescents under the age of 18 should not take this medicine.

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 Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil.

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 Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil

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:

- ciclosporine (used for example, after organ transplants)
- blood thinners e.g. warfarin, acenocoumarol or fluindione (their blood thinning effect and the risk of bleeding may be increased while taken together with this medicine), ticagrelor or clopidogrel
- 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)
- hormone replacement therapy
- 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 Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil or they could change the effects of Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil.

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 Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil. Taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil with fusidic acid may rarely lead to muscle weakness, tenderness or pain (*rhabdomyolysis*). See more information regarding *rhabdomyolysis* in section 4.

Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil with food and drink

Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil may be taken at any time of the day, preferably with food to avoid abdominal discomfort.

Pregnancy and breast-feeding

Do not take Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil if you are pregnant or breast-feeding. If you become pregnant while taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil **stop taking it immediately** and tell your doctor. Women should avoid becoming pregnant while taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil 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 taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil – it will not affect their ability. However, some people feel dizzy during treatment with Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil. If you feel dizzy, consult your doctor before attempting to drive or use machines.

Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil may contain traces of soybean oil.

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

3. How to take Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil

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

Usual doses

The recommended dose is 4 capsules daily.

Taking your capsules

Swallow each capsule whole. Take the capsules with food to avoid abdominal discomfort.

Take Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil once daily. You can take it at any time of the day. Try to take your capsule 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 Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil that is right for you.

If you take more Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil 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 are taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil.

If you forget to take Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil

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 Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil

Talk to your doctor if you want to stop taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil. Your cholesterol and triglyceride levels might increase again if you stop taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil.

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 Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil 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 Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil 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*.

Side effects associated with rosuvastatin

Common side effects (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 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 Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil

Rare 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, stop taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil and seek medical help immediately

- Muscle damage in adults – as a precaution, **stop taking Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil 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.

Very rare 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)

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

Side effects associated with omega-3-acid ethyl esters 90

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

- Irregular, rapid rhythm of the heart
- Stomach problems like abdominal distension, pain, constipation, diarrhoea, indigestion (dyspepsia), gas, belching (eructation), acid reflux, feeling sick (nausea) and being sick (vomiting)

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

- High blood sugar levels
- Gout
- Dizziness
- Problems with taste
- Headache
- Low blood pressure
- Nose bleed
- Blood in your stools
- Rash

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

- Allergic reactions
- Itchy rash (hives or urticaria)
- Liver disorders, with possible changes in the results of certain blood tests

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

- Itching

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting](#)

system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil

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

Store below 25 °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 Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil contains

- The active substances are rosuvastatin and omega-3-acid ethyl esters 90.
- The other ingredients are gelatin, glycerol (E422), hypromellose 2910, Amino Methacrylate Copolymer (=Eudragit® E PO), magnesium oxide (E530), triethyl citrate (E1505).

May contain traces of soybean oil.

What Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil looks like and contents of the pack

White, film-coated, oblong-shaped soft capsules filled with light yellow oil.

oPA/Al/PVC – Al blisters in a cardboard carton: 28 or 32 soft capsules.

PVC/Al blisters in a pillow bag and a cardboard carton: 28 or 30 soft capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Houder van de vergunning

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Fabrikant

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