

## Package leaflet: information for the user

**Atoris, 10 mg film-coated tablets**

**Atoris, 20 mg film-coated tablets**

**Atoris, 40 mg film-coated tablets**

atorvastatin

**Read all of this leaflet carefully before you start using 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 symptoms 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 Atoris is and what it is used for
2. What you need to know before you take Atoris
3. How to take Atoris
4. Possible side effects
5. How to store Atoris
6. Contents of the pack and other information

### **1. What Atoris is and what it is used for**

Atoris belongs to a group of medicines known as statins, which are medicines that regulate lipid (fat) levels in the blood.

Atoris tablets are used to lower lipid levels, such as cholesterol and triglycerides, in the blood, when a low-fat diet and life style changes on their own have failed. If you are at an increased risk of heart disease, Atoris can also be used to reduce such risk even if your blood cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.

### **2. What you need to know before you take Atoris**

#### **Do not take Atoris**

- If you are allergic to atorvastatin, other medicines that regulate lipid levels, or any of the other ingredients of this medicine (listed in section 6).
- If you have or have had a liver disease.
- If you have had any unexplained abnormal blood tests for liver function.
- If you are a woman of fertile age and not using reliable contraception.
- If you are pregnant or planning to have a baby.
- If you are breast-feeding.
- If you are taking a combination of glecaprevir / pibrentasvir for the treatment of hepatitis C.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Atoris.

Atoris may not be suitable for you for the following reasons:

- If you have severe respiratory failure.
- If you are taking or have taken, orally or by injection, a medicine called fusidic acid (a medicine for bacterial infections) in the last 7 days. The combination of fusidic acid and Atoris can lead to serious muscle problems (rhabdomyolysis).
- If you have previously had a stroke with a brain haemorrhage, or have small pockets of fluid in the brain from previous strokes.

- If you have kidney problems.
- If you have an underactive thyroid gland (hypothyroidism).
- If you have had repeated or unexplained muscle aches or have a personal or family history of muscular disease.
- If you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other statins or fibrates).
- If you regularly drink large amounts of alcohol.
- If you have a history of liver disease.

If you are over 70 years of age.

If any of the statements listed above apply to you, your doctor will need to carry out a blood test before and possibly during your treatment with Atoris to predict your risk of muscle-related side effects. The risk of muscle-related side effects, e.g. rhabdomyolysis, is known to increase when certain medicines are taken at the same time with Atoris (see section 2 “Other medicines and Atoris”).

Tell your doctor or pharmacist if you experience continuous muscle weakness. Additional tests and medicines may be needed to diagnose and treat this.

Your doctor will check for diabetes or the risk of developing diabetes during the treatment with Atoris. You are at an increased risk of developing diabetes when your blood sugar and blood lipid levels are high, you are overweight or have high blood pressure.

### **Other medicines and Atoris**

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

Some medicines may change the effect of Atoris or vice versa – their effect may be changed by Atoris. This type of interaction could make one or both of the medicines less effective. Alternatively, it could increase the risk or severity of side effects, including the important muscle damaging condition known as rhabdomyolysis (see section 4):

- Medicines used to alter the way your immune system works, e.g. cyclosporine.
- Certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampicin, fusidic acid.
- Other medicines that regulate blood lipid levels, e.g. gemfibrozil, other fibrates, such as colestipol.
- Some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem.
- Medicines used for treating arrhythmia, e.g. digoxin, verapamil, amiodarone.
- Letermovir – a drug that prevents cytomegalovirus.
- Medicines used in the treatment of HIV, e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, the combination of tipranavir and ritonavir etc.
- Some medicines used in the treatment of hepatitis C, e.g. telaprevir, boceprevir and a combination of glecaprevir/pibrentasvir, ledipasir/sofosbuvir.
- Other medicines that may interact with Atoris include ezetimibe (which lowers cholesterol), warfarin (which reduces blood clotting), oral contraceptives, stiripentol (an anticonvulsant for epilepsy), cimetidine (used for heartburn and peptic ulcers), phenazone (a painkiller), colchicine (used to treat gout) and antacids (medicines for indigestion, which contain aluminium or magnesium).
- Medicines obtained without a prescription: St. John’s Wort.
- 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 start taking Atoris again. Taking Atoris with fusidic acid may in rare cases lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### **Atoris with food, drink and alcohol**

See section 3 “How to take Atoris”. Please note the following:

#### *Grapefruit juice*

Do not drink more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice can change the effectiveness of Atoris.

#### *Alcohol*

Avoid drinking too much alcohol while taking this medicine. See section 2 “Warnings and precautions” for details.

### **Pregnancy and breast-feeding**

Do not take Atoris if you are pregnant or planning to have a baby.

Do not take Atoris if you are able to have a baby, unless you are using reliable contraceptive measures.

Do not take Atoris if you are breast-feeding.

The safety of Atoris during pregnancy and breast-feeding has not yet been proven. Talk to your doctor or pharmacist before using this medicine.

### **Driving and using machines**

Normally, this medicine does not affect your ability to drive or use machines. Do not drive if you feel that this medicine affects your ability to drive. Do not use any machines or tools if you feel that this medicine affects your ability to use them.

### **Atoris contains lactose and sodium**

If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before using this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially ‘sodium-free’.

## **3. How to take Atoris**

Before starting treatment, your doctor will place you on a low-cholesterol diet, which you should also maintain during treatment with Atoris.

The usual starting dose of Atoris is 10 mg once a day in adults and children aged 10 years or older. If necessary, the dose may be increased by your doctor to the level required for you. Your doctor will adapt the dose at intervals of 4 weeks or more. The maximum dose of Atoris is 80 mg once a day for adults and 20 mg once a day for children.

Atoris tablets should be swallowed whole with a drink of water, and can be taken at any time of day, with or without food. However, try to take your tablets at the same time every day.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**The duration of the treatment with Atoris is determined by your doctor.**

**If you feel that the effect of Atoris is too strong or too weak, talk to your doctor or pharmacist.**

#### **If you take more Atoris than you should**

If you accidentally take too many Atoris tablets (more than your usual daily dose), contact your doctor or nearest hospital for advice.

#### **If you forget to use Atoris**

If you forget to take a dose, 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 Atoris**

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.

**If any of the following side effects or symptoms get serious, stop taking the tablets and tell your doctor immediately or go to the emergency department of the nearest hospital.**

Rare: (may affect up to 1 user in 1,000):

- Severe allergic reaction that causes swelling of the face, tongue and throat, which can cause great difficulty in breathing.
- Serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, and genitals, and fever. Skin rash with pinkish-red blotches, especially on the palms of hands or the soles of feet, which may blister.
- Muscle weakness, tenderness, pain, tear or change in urine color to reddish brown; particularly, if at the same time you feel unwell or have a high fever, which may be caused by an abnormal muscle breakdown (rhabdomyolysis). The abnormal muscle breakdown may remain even after you have stopped taking atorvastatin. It can be life-threatening and lead to kidney problems.

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

- Unexpected or unusual bleeding or bruising may be suggestive of liver damage. Talk to your doctor as soon as possible.
- Lupus-like syndrome (including skin rash, joint problems and effects on blood parameters).

### **Other possible side effects that you may get when taking Atoris:**

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

- Inflammation of the nasal passages, sore throat, nose bleed.
- Allergic reactions.
- Increase in blood sugar levels (if you have diabetes, continue to carefully monitor your blood sugar levels).  
Increase in blood creatine kinase levels.
- Headache.
- Nausea, constipation, intestinal gas, indigestion, diarrhoea.
- Joint pain, muscle pain and back pain.
- Blood test results that show abnormal liver function.

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

- Anorexia (loss of appetite), weight gain, decrease in blood sugar content (if you have diabetes you should continue to carefully monitor your blood sugar content).
- Nightmares, insomnia.
- Dizziness, numbness or tingling in the fingers and toes, reduced sensation to pain or touch, change in the sense of taste, memory loss.
- Blurred vision.
- Ringing in the ears and/or head.
- Vomiting, belching, upper and lower abdominal pain, pancreatitis which may cause abdominal pain
- Inflammation of the liver.
- Rash, skin rash and -itching, hives, hair loss.
- Neck pain, muscle fatigue.
- Fatigue, feeling unwell, weakness, chest pain, swelling, especially in the ankles, raised body temperature.
- Urine tests that are positive for white blood cells.

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

- Visual disturbances.
- Unexpected bleeding or bruising.
- Cholestasis
- Tendon injury.

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

- An allergic reaction – symptoms may include sudden dyspnoea and pain or tightness in the chest, swelling of the eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse.
- Hearing loss.
- Gynecomastia (breast enlargement in men and women)

Unknown (incidence cannot be estimated from available data):

- Constant muscle weakness.

Possible side effects reported with the use of some statins (medicines of the same type):

- Sexual difficulties.
- Depression.
- Breathing difficulties, including persistent cough and/or shortness of breath or fever.
- Diabetes. This is more likely if your blood sugar and blood lipid levels are high, you are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

### **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](http://www.ravimiamet.ee). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Atoris**

Keep this medicine out of the sight and reach of children.

Do not store at a temperature higher than 25 °C.

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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Atoris contains**

- The active substance is atorvastatin. Each tablet contains 10 mg, 20 mg or 40 mg of atorvastatin (as a calcium salt).
- Atoris 10 mg and 20 mg film-coated tablets:  
The other excipients are: povidone, sodium lauryl phosphate, calcium carbonate (E170), microcrystalline cellulose (E460), lactose monohydrate, croscarmellose sodium (E468), magnesium stearate (E470b), talc (E553b) in the contents of the tablet, and titanium dioxide (E171), macrogol 3000, polyvinyl alcohol in the coating of the tablet.
- Atoris 40 mg film-coated tablets:  
The other excipients are: povidone, sodium lauryl phosphate, calcium carbonate (E170), microcrystalline cellulose (E460), lactose monohydrate, croscarmellose sodium (E468), crospovidone, magnesium stearate (E470b) in the contents of the tablet, and hypromellose (E464), titanium dioxide (E171), macrogol 400 in the coating of the tablet.

**What Atoris looks like and contents of the pack**

Atoris 10 mg, 20 mg, 40 mg tablets are white, round, double-convex and film-coated.

Atoris 10 mg tablets: 30 tablets in a box.

Atoris 20 mg tablets: 30 tablets in a box.

Atoris 40 mg tablets: 30, 60 or 90 tablets in a box.

**Marketing Authorisation Holder and Manufacturer**

KRKA, d.d., Novo mesto

Šmarješka cesta 6

8501 Novo mesto

Slovenia

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

KRKA, d.d., Novo mesto Estonian subsidiary

Pärnu mnt 141

11314 Tallinn

Phone +372 6671658

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