

ATORIS FILM-COATED TABLET

Atorvastatin (10mg, 20mg, 40mg)

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What Atoris is used for

Atoris is used to:

- lower cholesterol and other fats (triglycerides) in the blood when healthy diet and life style have failed.
- reduce risk of heart problems even if your cholesterol levels are normal.

How Atoris works

Atoris contains active ingredient atorvastatin, which belongs in the statin group. Atoris works by inhibiting the production of cholesterol in your liver.

Before you use Atoris

- When you must not use it

- if you are hypersensitive (allergic) to atorvastatin, other statins or to any other ingredients of this medicine (listed in Product Description)
- if you have or have ever had liver problems
- If you are taking glecaprevir/pibrentasvir (antiviral medication for hepatitis C)

- Before you start to use it

Talk to your doctor or pharmacist before taking Atoris:

- if you are taking or have taken a medicine that may interact with Atoris and cause muscle problems (refer to *Taking other medicines*),
- if you have had a previous stroke with bleeding into the brain,
- if you have kidney problems,
- if you have an under-active thyroid gland,
- if you or your family have history of muscle weakness, inflammation or muscle cramps, aches, or pains that are severe, because it may leads to rhabdomyolysis (syndrome caused by injury to skeletal muscle).
- if you have had previous muscular problems during treatment with

other lipid-lowering medicines (e.g. other '-statin' or '-fibrate' medicines),

- if you regularly drink a large amount of alcohol,
- if you have diabetes,
- if you have genetic intolerance to certain sugar,
- 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.

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your Atoris treatment to determine 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.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

Do not take Atoris if you are pregnant, as it may potentially cause harm to your baby. If you could get pregnant while receiving Atoris, a reliable form of contraception should always be used.

It is unknown whether Atoris secreted into the breastmilk or not, however, due to the risk of side effects in the baby, breastfeeding is not recommended while taking Atoris.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Inform your doctor or pharmacist if you are taking:

- cyclosporine (medicine to prevent rejection after organ transplant)
- certain antibiotics medicines, e.g. erythromycin, clarithromycin, telithromycin, rifampin, fusidic acid

- certain antifungal medicines, e.g. ketoconazole, itraconazole, voriconazole, posaconazole
- other medicines to reduce cholesterol and other fats, e.g. gemfibrozil, fibrates, colestipol, niacin, ezetimibe
- some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem
- medicines to regulate your heart rhythm e.g. digoxin
- letermovir (medicine to treat cytomegalovirus infections)
- medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, tipranavir, etc.
- some medicines used in the treatment of hepatitis C e.g. telaprevir, boceprevir and the combination of elbasvir/grazoprevir, ledipasvir/sofosbuvir
- oral contraceptives
- stiripentol (used for epilepsy)
- colchicine (used to treat gout)
- antacids (indigestion products containing aluminium or magnesium)

How to use Atoris

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

Adult, elderly and children 10 years and above:

Your doctor will determine the dose based on your diagnosis, as well as cholesterol or lipid level.

The usual starting dose is 10mg once per day. The maximum dose may be up to 80 mg per day.

- When to use it

Take once every day, with or without food. Preferably at the same time every day.

- How long to use it

Use this medicine for as the duration that your doctor recommends.

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- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Atoris

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Atoris.

Tell your doctor immediately if you become pregnant while using this medication.

Take Atoris only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Atoris to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Do not take grapefruit juice because grapefruit juice can increase the side effects of Atoris especially more than 1.2 Litres of grapefruit juice per day.

Avoid drinking alcohol while taking this medicine.

Driving and using machines

Atoris does not affect your ability to drive or operate machinery.

Side effects

Like all medicines, Atoris can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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.

If you have muscle problems that do not go away even after your doctor has told you to stop taking Atoris, please see your doctor. Your doctor may need to do further tests to diagnose the cause of your muscle problems.

Most frequent side effects:

- common cold,
- high sugar in blood,
- sore throat, nose bleed,
- nausea, diarrhea, indigestion, wind,
- pain related to joint, limbs, muscle and bone,
- liver function test abnormal.

Other side effects:

- nightmares,
- blurred vision,
- ringing in the ears,
- abdominal discomfort, belching,
- liver inflammation,
- hives,
- muscle fatigue, neck pain, weakness,
- fever,
- white blood cells in urine.

Other reported side effects (post-marketing):

- low platelets,
- allergic reactions (may become severe),
- tendon rupture,
- weight gain,
- sensation disturbance, loss of memory, dizziness, taste disturbances,
- inflammation of pancreas,
- severe skin reaction: skin reddening, blisters, rash, fever, sore throat or eye irritation,
- abnormal muscle breakdown (rhabdomyolysis), constant muscle weakness, back pain,
- chest pain, limbs swelling, fatigue,
- 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Atoris

- Storage

Keep out of the reach and sight of children.

Do not store above 30 °C.

Store in the original package.

Do not use your medicine after the expiry date, which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

White, round, slightly convex, film-coated tablet, bevel-edged.

- Ingredients

- Active ingredient
 - Atoris 10 mg contains atorvastatin calcium 10 mg.
 - Atoris 20 mg contains atorvastatin calcium 20 mg.
 - Atoris 40 mg contains atorvastatin calcium 40 mg.

- Inactive ingredients

Sodium hydroxide, sodium laurilsulfate, hydroxypropylcellulose, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, crospovidone, magnesium stearate in the tablet core and polyvinyl alcohol,

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titanium dioxide (E171), macrogol 3000
and talc in the film-coating.

- MAL number(s):

10 mg: MAL11030084AZ

20 mg: MAL11030081AZ

40 mg: MAL11030082AZ

Manufacturer

KRKA, d.d., Novo mesto,
Šmarješka cesta 6,
8501 Novo mesto,
Slovenia

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.,
Lot 5979, Jalan Teratai,
5 ½ Mile off Jalan Meru,
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26/06/2025

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