

Package leaflet: Information for the user

Olmenor 10 mg film-coated tablets

Olmesartan medoxomil

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 Olmenor is and what it is used for
2. What you need to know before you take Olmenor
3. How to take Olmenor
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1. What Olmenor is and what it is used for

Olmenor belongs to a group of medicines called angiotensin-II receptor antagonists. It lowers blood pressure by relaxing the blood vessels.

Olmenor is used for the treatment of high blood pressure (also known as ‘hypertension’). High blood pressure can damage blood vessels in organs such as the heart, kidneys, brain and eyes. In some cases this may lead to a heart attack, heart or kidney failure, stroke or blindness. Usually high blood pressure has no symptoms. It is important to have your blood pressure checked to prevent damage occurring.

High blood pressure can be controlled with medicines such as Olmenor tablets. Your doctor has probably also recommended that you make some changes in your lifestyle to help lower your blood pressure (for example losing weight, giving up smoking, reducing the amount of alcohol you drink and reducing the amount of salt in your diet). Your doctor may also have urged you to take regular exercise, such as walking or swimming. It is important to follow this advice from your doctor.

2. What you need to know before you take Olmenor

Do not take Olmenor

- If you are allergic to olmesartan medoxomil or any of the other ingredients of this medicine (listed in section 6).
- If you are more than 3 months pregnant. (It is also better to avoid Olmenor tablets in early pregnancy – see section Pregnancy).
- If you suffer from yellowing of the skin and eyes (jaundice) or problems with drainage of the bile from the gallbladder (biliary obstruction, e.g., gallstones).
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions

Talk to your doctor before you start taking Olmenor.

Tell your doctor if you are taking any of the following medicines to treat high blood pressure (hypertension):

- an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
- aliskiren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading "Do not take Olmenor".

Tell your doctor if you have any of the following health problems:

- Kidney problems.
- Liver disease.
- Heart failure or problems with your heart valves or heart muscle.
- Severe vomiting, diarrhea, treatment with high doses of water tablets (diuretics) or if you are on a low salt diet.
- Increased levels of potassium in your blood.
- Problems with your adrenal glands.

Contact your doctor if you experience diarrhea that is severe, persistent and causes substantial weight loss. Your doctor may evaluate your symptoms and decide on how to continue your blood pressure medication.

As with any medicine which reduces blood pressure, an excessive drop in blood pressure in patients with blood flow disturbances of the heart or brain could lead to a heart attack or stroke. Your doctor will therefore check your blood pressure carefully.

You must tell your doctor if you think you are or might become pregnant. Olmenor is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see section Pregnancy).

Children and adolescents

Olmenor is not recommended for children and adolescents under 18 years of age.

Other medicines and Olmenor

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

- Other blood pressure lowering medicines, as the effect of Olmenor can be increased.
Your doctor may need to change your dose and/or to take other precautions:
If you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take Olmenor" and "Warnings and precautions").
- Potassium supplements, a salt substitutes which contain potassium, water tablets (diuretics) or heparin (for thinning the blood). Using these medicines at the same time as Olmenor may raise the levels of potassium in your blood.
- Lithium (a medicine used to treat mood swings and some types of depression) used at the same time as Olmenor may increase the toxicity of lithium. If you have to take lithium, your doctor will measure your lithium blood levels.

- Non-Steroidal Anti-Inflammatory (NSAIDs) medicines (medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis) used at the same time as Olmenor may increase the risk of kidney failure and the effect of Olmenor can be decreased by NSAIDs.
- Colesevelam hydrochloride, a drug that lowers the level of cholesterol in your blood, as the effect of olmesartan may be decreased. Your doctor may advise you to take Olmenor at least 4 hours before colesevelam hydrochloride.
- Certain antacids (indigestion remedies), as the effect of Olmenor can be slightly decreased.

Elderly patients

If you are 65 years or over and your doctor decides to increase your dose of olmesartan medoxomil to 40 mg daily, then you need to have your blood pressure regularly checked by your doctor to make sure that your blood pressure does not become too low.

Black patients

As with other similar drugs the blood pressure lowering effect of Olmenor is somewhat less in black patients.

Olmenor with food and drink

Olmenor can be taken with or without food.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are or might become pregnant. Your doctor will normally advise you to stop taking Olmenor before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Olmenor. Olmenor is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Brest-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Olmenor is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You may feel sleepy or dizzy while being treated for your high blood pressure. If this happens, do not drive or use machines until the symptoms wear off. Talk to your doctor.

Olmenor contains lactose

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

3. How to take Olmenor

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

The recommended starting dose is one 10 mg tablet of Olmenor a day. However, if your blood pressure is not controlled, your doctor may decide to change your dose up to 20 or 40 mg a day, or prescribe additional medicines.

In patients with mild to moderate kidney disease, the dose will not be higher than 20 mg once a day.

Tablets may be taken with or without food. Take the tablets with a sufficient amount of water (e.g. one glass). If possible, take your daily dose at the same time each day, for example at breakfast time.

If you take more Olmenor than you should

If you take more tablets than you should or if a child accidentally swallows some, go to your doctor or nearest emergency department immediately and take your medicine pack with you.

In case of overdose or accidental ingestion, contact your doctor or pharmacist at once, or go to the nearest hospital, indicating the medicine and the amount taken (or received).

If you forget to take Olmenor

If you forget a dose, take your normal dose on the following day as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Olmenor

It is important to continue to take Olmenor unless your doctor tells you to stop.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If they do occur, they are often mild and do not require treatment to be stopped.

Although not many people may get them, the following two side effects can be serious:

On rare occasions (may affect up to 1 in 1,000 people) the following allergic reactions that may affect the whole body have been reported: swelling of the face, mouth and/or larynx, together with itching and skin rash. **If this happens, stop taking Olmenor and contact your doctor immediately.**

Rarely (but slightly more often in elderly people) Olmenor can cause the blood pressure to fall too low in susceptible individuals or as the result of an allergic reaction. This could cause severe light-headedness or fainting. **If this occurs stop taking Olmenor, contact your doctor immediately and lie down flat.**

These are the other side effects known about so far with Olmenor:

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

Dizziness, headache, nausea, indigestion, diarrhea, stomach ache, gastroenteritis, tiredness, sore throat, runny or stuffy nose, bronchitis, flu-like symptoms, cough, pain, pain in the chest, back, bones or joints, infection of the urinary tract, swelling of ankles, feet, legs, hands or arms, blood in the urine.

Some changes in blood test results have also been seen and include the following: increased fat levels (hypertriglyceridemia), increased uric acid levels (hyperuricemia), rise in blood urea, increases in tests of liver and muscle function.

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

Quick allergic reactions that may affect the whole body and may cause breathing problems as well as a rapid fall of blood pressure that may even lead to fainting (anaphylactic reactions), vertigo, vomiting, weakness, feeling unwell, muscular pain, skin rash, allergic skin rash, itching, exanthema (skin eruption), skin lumps (wheals), angina (pain or uncomfortable feeling in the chest).

In blood tests a reduction of the numbers of a type of blood cell, known as platelets has been seen (thrombocytopenia).

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

Lack of energy, muscle cramps, impaired kidney function, kidney failure.

Some changes in blood test results have also been seen. These include increased potassium levels (hyperkalemia) and increased levels of compounds related to kidney function.

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

5. How to store Olmenor

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 container and on the blister (after “EXP”). The expiry date refers to the last day of that month.

Do not store above 30 °C.

Do not throw away any medicines via wastewater or household waste. Deposit containers and medicines you no longer need at the recycling containers at your pharmacy. If you are not sure, ask your pharmacist how to throw away medicines and containers you no longer need. These measures will help protect the environment.

6. Contents of the pack and other information

What Olmenor contains

The active substance is olmesartan medoxomil.

Each film-coated tablet contains 10 mg of olmesartan medoxomil.

The other ingredients are: microcrystalline cellulose, lactose monohydrate, hydroxypropylcellulose, low substituted hydroxypropylcellulose, magnesium stearate, titanium dioxide (E 171), talc, macrogol 600 and hydroxypropyl methylcellulose (See section 2 “Olmenor contains lactose”).

What Olmenor looks like and contents of the pack

Olmenor 10 mg film-coated tablets are white, round and biconvex.
Olmenor 10 mg film-coated tablets are available in packs of 28 tablets.

Marketing Authorization Holder and Manufacturer

LABORATORIOS NORMON, S.A.
Ronda de Valdecarrizo, 6 – 28760 Tres Cantos – Madrid (SPAIN)

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