

PACKAGE LEAFLET

Package leaflet: Information for the user

Olmesartan medoxomil 10 mg Film-coated Tablets
Olmesartan medoxomil 20 mg Film-coated Tablets
Olmesartan medoxomil 40 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 Olmesartan medoxomil is and what it is used for
2. What you need to know before you take Olmesartan medoxomil
3. How to take Olmesartan medoxomil
4. Possible side effects
5. How to store Olmesartan medoxomil
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1. What Olmesartan medoxomil is and what it is used for

Olmesartan medoxomil belongs to a group of medicines called angiotensin-II receptor antagonists. They lower blood pressure by relaxing the blood vessels.

This medicine is used for the treatment of high blood pressure (also known as ‘hypertension’) in adults and in children and adolescents aged 6 to less than 18 years. 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 olmesartan medoxomil 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 Olmesartan medoxomil

Do not take Olmesartan medoxomil:

- 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 this medicine in early pregnancy – see pregnancy section.)
- 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 or pharmacist before taking olmesartan medoxomil

- If you have kidney problems
- If you have liver disease
- If you have heart failure or problems with your heart valves or heart muscle
- If you are diabetic, have severe vomiting, diarrhoea, treatment with high doses of water tablets (diuretics) or if you are on a low salt diet
- If you have increased levels of potassium in your blood
- If you have problems with your adrenal glands.
- If you are taking any of the following medicines used to treat high blood pressure:
 - 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 Olmesartan medoxomil”

During treatment

Contact your doctor if you experience severe, persistent diarrhoea and 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. This medicine 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 pregnancy section).

Children and adolescents

Olmesartan medoxomil has been studied in children and adolescents. For more information, talk to your doctor.

This medicine is not recommended for children from 1 year to less than 6 years and should not be used in children under the age of 1 year as no experience is available.

Elderly

If you are over 65 years of age 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 this medicine is somewhat less in black patients.

Other medicines and Olmesartan medoxomil

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

- Potassium supplements, a salt substitute which contains potassium, water tablets (diuretics) or heparin (for thinning the blood). Using these medicines at the same time as olmesartan medoxomil 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 olmesartan medoxomil 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, e.g. ibuprofen, aceclofenac) used at the same time as olmesartan medoxomil may increase the risk of kidney failure and the effect of olmesartan medoxomil can be decreased by NSAIDs.
- Colesevelam hydrochloride, a medicine that lowers the level of cholesterol in your blood, as the effect of olmesartan medoxomil may be decreased. Your doctor may advise you to take olmesartan medoxomil at least 4 hours before colesevelam hydrochloride.
- Other blood pressure lowering medicines, as the effect of olmesartan medoxomil can be increased.
- Certain antacids (indigestion remedies), as the effect of olmesartan medoxomil can be slightly decreased.

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 Olmesartan medoxomil” and “Warnings and precautions”).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant or if you are planning to have a baby. Your doctor will normally advise you to stop taking this medicine before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead.

This medicine 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.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. This medicine 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.

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. Ask your doctor for advice.

Olmesartan medoxomil contains sodium

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

3. How to take Olmesartan medoxomil

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

Adults

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

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

The tablets can be taken with or without food. Swallow the tablets whole with a sufficient amount of water (e.g. one glass). The tablets should not be chewed. If possible, take your daily dose at the same time each day, for example at breakfast time.

Children and adolescents from 6 to less than 18 years of age:

The recommended starting dose is 10 mg once daily. If the patient's blood pressure is not adequately controlled, the doctor may decide to change the dose up to 20 or 40 mg once a day. In children who weigh

less than 35 kg, the dose will not be higher than 20 mg once a day.

If you take more Olmesartan medoxomil 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.

If you forget to take Olmesartan medoxomil

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 Olmesartan medoxomil

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

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 they do occur, they are often mild and do not require treatment to be stopped.

Although not many people may get them, **the following side effects can be serious. If you notice any of the following you should contact your doctor or go to your nearest hospital emergency department immediately:**

Uncommon (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).
- Pain or a tight or heavy feeling in the chest, especially when exercising. These may be signs of problems with your heart (angina).

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

- Swelling of the face, mouth and/or larynx (voice box) together with itching and rash may occur during treatment with this medicine. **If this happens stop taking this medicine and contact your doctor immediately.**

- Rarely (but slightly more often in elderly patients), this medicine can cause the blood pressure to fall too low in susceptible individuals or as a result of an allergic reaction. This could cause severe light-headedness or fainting. **If this occurs stop taking this medicine, contact your doctor immediately and lie down flat.**
- Difficulty or pain when urinating, with changes in the colour and amount of urine passed. Pain in the lower back, feeling or being sick, feeling generally unwell. These may be signs of serious problems with your kidneys.

Not known:

- If you experience yellowing of the whites of the eyes, dark urine, itching of the skin, even if you started therapy with Olmesartan medoxomil longer time ago, **contact your doctor immediately** who will evaluate your symptoms and decide on how to continue your blood pressure medication.

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

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

- Feeling dizzy, headache
- Feeling sick, indigestion, diarrhoea, stomach ache, gastroenteritis
- Feeling tired
- Sore throat, runny or stuffy nose, bronchitis, flu-like symptoms, cough
- Pain, particularly in the back, bones or joints
- Infection of the urinary tract
- Blood in the urine
- Swelling of ankles, feet, legs, hands, or arms.

Some changes in blood test results have also been seen:

- Increased fat levels (hypertriglyceridaemia)
- Increased uric acid levels (hyperuricaemia)
- Rise in blood urea
- Increases in tests of liver and muscle function.

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

- Spinning sensation (vertigo)
- Vomiting, weakness, feeling unwell
- Muscle pain
- Skin rash, allergic skin rash, itching, skin eruption (exanthema), skin lumps (wheals).

Some changes in blood test results have also been seen:

- A reduction of the number of type of blood cell, known as platelets (thrombocytopenia),

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

- Lack of energy
- Muscle cramps
- Reduced kidney function, which may cause you to pass urine more frequently, especially at night, and will be seen in a blood test
- Low blood pressure, which may cause you to feel dizzy or tired

Some changes in blood test results have also been seen:

- Increased potassium levels (hyperkalaemia)
- Increased levels of compounds related to kidney function.

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

- Severe persistent diarrhoea and substantial weight loss.

Additional side effects in children and adolescents:

In children, side effects are similar to those reported in adults. However, dizziness and headache are seen more often in children, and nose bleeding is a common side effect seen in children only.

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:

HPRA Pharmacovigilance,
Website: www.hpra.ie.

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

5. How to store Olmesartan medoxomil

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

Do not store above 25°C. Store in the original container in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton and blister/bottle after 'EXP'. The expiry date refers to the last day of that month.

For plastic containers:

20mg tablets use within 100 days after first opening

10mg tablets: use within 180 days after first opening.

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 Olmesartan medoxomil contains**

- The active substance is olmesartan medoxomil
- Each film-coated tablet contains 10 mg, 20 mg or 40 mg olmesartan medoxomil
- The other ingredients in the tablet core are croscarmellose sodium, mannitol, microcrystalline cellulose, low-substituted hydroxypropyl cellulose, colloidal anhydrous silica, magnesium stearate, sodium lauryl sulfate
- The film-coating contains hypromellose, titanium dioxide (E171), macrogol, talc.

What Olmesartan medoxomil looks like and contents of the pack

Olmesartan medoxomil 10 mg film-coated tablets are white, film coated, round, biconvex bevelled edge tablets marked with 'M' on one side of the tablet and 'O1' on the other side.

Olmesartan medoxomil 20 mg film-coated tablets are white, film coated, round, biconvex bevelled edge tablets marked with 'M' on one side of the tablet and 'O2' on the other side.

Olmesartan medoxomil 40 mg film-coated tablets are white, film coated, oval, biconvex bevelled edge tablets marked with 'M' on one side of the tablet and 'O4' on the other side.

Olmesartan medoxomil film-coated tablets are available in blister packs of 14, 28, 28x1, 30, 50x1, 56, 90 and 98 film-coated tablets. The 10 mg tablets are also available in plastic bottles of 500 film-

coated tablets and the 20 mg tablets are also available in plastic bottles of 98 and 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturer

Generics [UK] Ltd, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

McDermott Laboratories Ltd t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Mylan Hungary Kft, H-2900 Komárom, Mylan útca 1, Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

Greece:	Olmesartan / Mylan 10 mg, 20 mg & 40 mg
Ireland:	Olmesartan medoxomil 10 mg, 20 mg & 40 mg Film-coated tablets
Italy:	Olmesartan medoxomil Mylan 10, 20, 40 mg
Portugal:	Olmesartan medoxomilo Mylan
Spain:	Olmesartan MYLAN 10 mg - 20 mg - 40 mg comprimidos recubiertos EFG
The Netherlands:	Olmesartan medoxomil Mylan 10 mg/20 mg or 40 mg, filmomhulde tabletten
United Kingdom:	Olmesartan medoxomil 10 mg, 20 mg & 40 mg Film-coated tablets

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