

Olmesartan medoxomil 10 mg, 20 mg and 40 mg Film-coated Tablets
olmesartan medoxomil

- 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.

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
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6. Contents of the pack and other information

High blood pressure can be controlled with medicines such as Olmesartan medoxomil . 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.

- 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 Olmesartan medoxomil 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.

- 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

- Kidney problems
- Liver disease
- Heart failure or problems with your heart valves or heart muscle.
- Severe vomiting, diarrhoea, 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.

You must tell your doctor if you think you are (or might become) pregnant. Olmesartan medoxomil 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).

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.

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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 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.

Use in children and adolescents with high blood pressure

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 tablet.

If you stop taking Olmesartan medoxomil

It is important to continue to take Olmesartan medoxomil 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 (voice box) together with itching and rash may occur during treatment with Olmesartan medoxomil.

If this happens stop taking Olmesartan medoxomil and contact your doctor immediately.

Rarely (but slightly more often in older people) Olmesartan medoxomil 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 Olmesartan medoxomil, contact your doctor immediately and lie down flat.

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

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

- dizziness
- headache
- nausea
- indigestion
- diarrhoea
- 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 (hypertriglyceridaemia)
 - increased uric acid levels (hyperuricaemia)
 - 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), swelling of the face, 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

(hyperkalaemia) and increased levels of compounds related to kidney function.

Additional side effect 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:

Ireland

HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie.

United Kingdom

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

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 use this medicine after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 tablet contains 10 mg, 20 mg or 40 mg olmesartan medoxomil.
- The other ingredient are cellulose microcrystalline, low substituted hydroxypropyl cellulose, lactose monohydrate, hydrogenated castor oil, magnesium Stearate, hypromellose, hydroxypropyl cellulose, Titanium Dioxide and talc

What Olmesartan medoxomil looks like and contents of the pack

Olmesartan medoxomil 10 mg tablets are white to off white, round film-coated tablets, debossed with 476 on one side and plain on the other side with a characteristic odour, approx. 6.3 mm in diameter.

Olmesartan medoxomil 20 mg tablets are white to off white, round film-coated tablets, debossed with 437 on one side and plain on the other side with a characteristic odour, approx. 8.6 mm in diameter.

Olmesartan medoxomil 40 mg tablets are white to off white, oval-shaped film-coated tablets debossed with 438 on one side and plain on the other side with a characteristic odour approx.15.3 mm in length and 7.2 mm in breadth.

Olmesartan medoxomil tablets are available in packs of 28, 30, 56, 90 and 98 film-coated tablets and packed in PVC/Alu/OPA – Alu blister packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Glenmark Pharmaceuticals Europe Limited
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United Kingdom.

Manufacturer

Glenmark Pharmaceuticals Europe Limited
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United Kingdom.

Glenmark Pharmaceuticals s.r.o.

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Czech Republic.

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

Netherlands	Olmesartan medoxomil Glenmark 10 mg/20mg/40mg filmomhulde tabletten
Spain	Olmesartan Viso Farmacéutica 10mg/20mg/40mg comprimidos recubiertos con película EFG
Germany	Olmesartan Glenmark 10 mg/20mg/40mg Filmtablette
United Kingdom	Olmesartan medoxomil 10 mg/20mg/40mg Film-coated Tablets
Ireland	Olmesartan medoxomil 10 mg/20mg/40mg Film-coated Tablets

This leaflet was last revised in 04/2017.

GLENMARK PHARMACEUTICALS LTD.		DATE: 18.04.2017		PANTONE SHADE N0: Black	
PRODUCT NAME: LEAFLET OLMESARTAN TABS UK		PKG. DEV.:		Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
ITEM CODE: 3010001 VERSION: 1824		RA		Regulatory Text	
PHARMACODE: YES BARCODE: NA		QA:		Entire Text	
COUNTRY: UK		PRODUCTION:		Machine Suitability	
LOCATION: Indore		REMARKS: NA			
PACK : folded:170X35MM					
ACTUAL SIZE: 170X370 MM					
SPECIFICATION: 40 GSM Bible Paper					