

Olmesartan Rowex 10mg Film-coated tablets
Olmesartan Rowex 20mg Film-coated tablets
Olmesartan Rowex 40mg 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 Rowex is and what it is used for
2. What you need to know before you take Olmesartan Rowex
3. How to take Olmesartan Rowex
4. Possible side effects
5. How to store Olmesartan Rowex
6. Contents of the pack and other information



1 What Olmesartan Rowex is and what it is used for

Olmesartan Rowex belongs to a group of medicines known as angiotensin II receptor antagonists. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them.

Olmesartan Rowex tablets are used to treat high blood pressure (hypertension).

2 What you need to know before you take Olmesartan Rowex

Do NOT take Olmesartan Rowex, if you:

- are **allergic** to olmesartan medoxomil or any of the other ingredients of this medicine (listed in section 6)
- have **biliary obstruction** (a problem with the drainage of the bile from the gall bladder)
- have **diabetes** or **impaired kidney function** and you are treated with a blood pressure lowering medicine containing **aliskiren**
- are **more than 3 months pregnant**. (It is also better to avoid Olmesartan Rowex in early pregnancy – see pregnancy section).

Warnings and precautions

Talk to your doctor before taking Olmesartan Rowex if you:

- have **heart, liver or kidney problems**
- have recently had **a kidney transplant**
- are on **haemodialysis**
- are **vomiting**, have recently been vomiting or **have diarrhoea**
- have a **disease of adrenal gland** (Conn’s disease – hyperaldosteronism)
- have **increased levels of potassium** in your blood
- 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 Rowex if you”

Contact your doctor if you experience diarrhoea 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.

You must tell your doctor if you think you are (or might become) pregnant. Olmesartan Rowex 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 Rowex is not recommended for children and adolescents under the age of 18.

Other medicines and Olmesartan Rowex

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

Olmesartan Rowex can affect the way some other medicines work and some medicines can have an effect on Olmesartan Rowex:

- **potassium supplements**, a salt substitute which contains potassium
- **water tablets** (diuretics)
- **heparin (blood thinning medication)**
- **lithium** (for treatment of mania or depression)
- Non-Steroidal Anti-Inflammatory (NSAIDs), medicines **for pain and inflammation**
- other medicines that **lower blood pressure**
- **colesevelam hydrochloride**, a medicine that lowers the level of cholesterol in your blood, as the effect of Olmesartan Rowex may be decreased. Your doctor may advise you to take Olmesartan Rowex at least 4 hours before colesevelam hydrochloride
- certain **indigestion medicines** (antacids).

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 Rowex if you” and “Warnings and precautions”).

Taking Olmesartan Rowex with food and drink

Food has no influence on the blood lowering effect of olmesartan medoxomil. Olmesartan Rowex is to be taken at about the same time each day (e.g. breakfast) with a glass of water.

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 Olmesartan Rowex before you become pregnant or as soon as you know you are

pregnant and will advise you to take another medicine instead of Olmesartan Rowex. Olmesartan Rowex 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. Olmesartan Rowex 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. Ask your doctor for advice.

Olmesartan Rowex contains lactose

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

3 How to take Olmesartan Rowex

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

It is recommended that Olmesartan Rowex be taken at about the same time each day, with or without food, for example at breakfast time.

Adults

The recommended starting dose of Olmesartan Rowex is 10 mg once daily. In patients whose blood pressure is not adequately controlled at this dose, the dose of Olmesartan Rowex may be increased to 20 mg once daily as the optimal dose. If additional blood pressure reduction is required, dose may be increased to a maximum of 40 mg daily or hydrochlorothiazide therapy may be added. Therapy should be adjusted according to blood pressure response. Most of the antihypertensive effect is attained within 2 to 8 weeks of initiation of treatment.

Use in the elderly

No initial dosage adjustment is necessary in elderly patients.

Use in impaired kidney function

The maximum dose in patients with mild to moderate kidney impairment is 20 mg Olmesartan Rowex once daily, owing to limited experience of higher dosages in this patient group. The use of this medicine in patients with severe kidney impairment is NOT recommended.

Use in impaired liver function

No initial dosage adjustment is required for patients with mild liver impairment. In patients with moderate liver impairment, an initial dose of 10 mg Olmesartan Rowex once daily is recommended and the maximum dose should not exceed 20 mg once daily. Use of this medicine in patients with severe liver impairment is NOT recommended.

Olmesartan Rowex should not be used in patients with biliary obstruction (see section 2 “Do not take Olmesartan Rowex if you”).

Children and adolescents

Olmesartan Rowex is not recommended for use in children below 18 years.

Use in black patients

The antihypertensive effect of Olmesartan Rowex is less in black than non-black patients. Consequently, the dose of this medicine is to be adjusted and concomitant therapy may be more frequently needed for blood pressure control in black patients.

If you take more Olmesartan Rowex than you should

If you (or someone else) take too many tablets, contact your nearest hospital casualty department or tell your doctor immediately. The most likely effect in the case of an overdose is low blood pressure. If marked low blood pressure occurs (symptoms such as dizziness or faintness may occur), lying down with the legs raised can help. However, if symptoms are severe, please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know what tablets were consumed.

If you forget to take Olmesartan Rowex

It is important to take your medicine every day. However, if you forget to take one or more doses, take it as soon as you remember and then continue with your normal schedule. Do not take a double dose to make up for a forgotten dose.

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If you stop taking Olmesartan Rowex

Always consult your doctor, if you wish to stop taking this medicine. Even if you feel well, it may be necessary to continue taking this medicine.

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.

Stop taking the tablets and contact your doctor immediately if you notice any of the following:

- an **allergic reaction**, symptoms of which include serious swelling of the face, lips, mouth, tongue, eyes or throat which are very rare (may affect up to 1 in 10,000 people) but **MUST** be treated immediately, usually in a hospital.
- **low blood pressure which causes light-headedness or fainting** (may affect up to 1 in 1,000 people). If this occurs you should seek medical attention and lie down flat.

Other possible side effects

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

- dizziness
- headache
- feeling sick
- indigestion, diarrhoea, stomach ache, gastroenteritis
- tiredness
- sore throat
- runny or stuffy nose
- bronchitis (inflammation of airways)
- flu-like symptoms
- cough
- pain in the chest, back, bones or joints
- infection of the urinary tract
- swelling of the 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 in the blood (hyperuricaemia)
- increases in tests of liver and muscle function.

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

- reduction of the numbers of a type of blood cell, known as platelets (thrombocytopenia)
- vertigo
- angina (pain or uncomfortable feeling in the chest)
- vomiting
- skin eruption (exanthema)
- skin rash, allergic skin rash
- hives
- itching
- muscular pain
- weakness
- feeling unwell.

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

- increased potassium levels (hyperkalaemia)
- muscle cramps
- impaired kidney function
- kidney failure
- lack of energy
- changes in blood test results have also been seen including increases in tests of kidney function.

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

- severe and persistent diarrhoea
- substantial weight loss.

Contact your doctor if you experience these symptoms. Your doctor may evaluate your symptoms and decide on how to continue your blood pressure medication.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Olmesartan Rowex

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 after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.
Store in the original package in order to protect from moisture.

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 Rowex contains

The active substance is olmesartan medoxomil.
The other ingredients are:

Tablet core:
Lactose Monohydrate
Cellulose, microcrystalline
Hydroxypropylcellulose
Colloidal silica, Anhydrous
Stearic acid

Tablet coating:
Hypromellose
Hydroxypropylcellulose
Macrogol 400
Titanium dioxide (E171)
Talc

What Olmesartan Rowex looks like and contents of the pack

Olmesartan Rowex 10mg Film-coated tablets
White, round, biconvex film-coated tablet with inscription ‘10’ on one side.
Dimension: 6.4 mm - 6.7 mm.

Olmesartan Rowex 20mg Film-coated tablets
White, round, biconvex film-coated tablet with inscription ‘20’ on one side.
Dimension: 8.5 mm – 8.8 mm.

Olmesartan Rowex 40mg Film-coated tablets
White, oval, biconvex film-coated tablet with inscription ‘40’ on one side.
Dimension: 14.9 mm – 15.2 mm x 7 mm - 7.3 mm.

Alu/Alu blisters available in pack sizes of 7, 10, 14, 28, 30, 56 and 98.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.
Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia.
Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

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

AT	Olmesartan Sandoz 10 mg - Filmtabletten Olmesartan Sandoz 20 mg - Filmtabletten Olmesartan Sandoz 40 mg - Filmtabletten
BE	Olmesartan Sandoz 10 mg filmomhulde tabletten Olmesartan Sandoz 20 mg filmomhulde tabletten Olmesartan Sandoz 40 mg filmomhulde tabletten
BG	Танзидор 10 mg филмирани таблетки Tansidor 10 mg film-coated tablets Танзидор 20 mg филмирани таблетки Tansidor 20 mg film-coated tablets Танзидор 40 mg филмирани таблетки Tansidor 40 mg film-coated tablets
DE	Olmesartan – 1 A Pharma 10 mg Filmtabletten Olmesartan – 1 A Pharma 20 mg Filmtabletten Olmesartan – 1 A Pharma 40 mg Filmtabletten
EL	Olmesartan/Sandoz
FR	OLMESARTAN MEDOXOMIL SANDOZ 10 mg, comprimé pelliculé OLMESARTAN MEDOXOMIL SANDOZ 20 mg, comprimé pelliculé OLMESARTAN MEDOXOMIL SANDOZ 40 mg, comprimé pelliculé
IE	Olmesartan Rowex 10mg Film-coated tablets Olmesartan Rowex 20mg Film-coated tablets Olmesartan Rowex 40mg Film-coated tablets
IT	olmesartan medoxomil Sandoz
NL	Olmesartan medoxomil Sandoz 10 mg, filmomhulde tabletten Olmesartan medoxomil Sandoz 20 mg, filmomhulde tabletten Olmesartan medoxomil Sandoz 40 mg, filmomhulde tabletten
PT	Olmesartan medoxomilo Teclave

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