

## **Package leaflet: Information for the user**

### **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 called angiotensin II receptor antagonists. They lower blood pressure by relaxing the blood vessels.

Olmesartan Rowex 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 Rowex 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 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).
- if you are more than 3 months pregnant. (It is also better to avoid Olmesartan Rowex 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 before using **Olmесartan Rowex**.

**Tell your doctor** 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 Rowex”.

**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, 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.

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 medicine.

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. 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).

### **Black patients**

As with other similar medicines the blood pressure lowering effect of Olmesartan Rowex is somewhat less in black patients.

### **Elderly**

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.

### **Children and adolescents**

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

### **Other medicines and Olmesartan Rowex**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

In particular, tell your doctor or pharmacist about any of the following:

- Other blood pressure lowering medicines, as the effect of this medicine 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 Olmesartan Rowex” and “Warnings and precautions”).

- 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 Rowex 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 Rowex may increase the toxicity of lithium. If you have to take lithium, your doctor will measure your lithium blood levels.
- Non-Steroidal Anti-Inflammatory drugs (NSAIDs) (medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis) used at the same time as Olmesartan Rowex may increase the risk of kidney failure and the effect of Olmesartan Rowex can be decreased by NSAIDs.
- 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 antacids (indigestion remedies), as the effect of Olmesartan Rowex can be slightly decreased.

### **Olmesartan Rowex with food and drink**

Olmesartan Rowex 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 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.

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.

### **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 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 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. The tablet should not be chewed.

#### **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 Rowex 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 Rowex**

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 Rowex**

It is important to continue to take Olmesartan Rowex 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:

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 Rowex and contact your doctor immediately.**

Rarely (but slightly more often in elderly 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 lightheadedness or fainting. **If this occurs stop taking Olmesartan Rowex, contact your doctor immediately and lie down flat.**

Frequency 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 Rowex a long 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 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 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 the national reporting system: HPRA Pharmacovigilance; website: [www.hpra.ie](http://www.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 blister and 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 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:**

BE	Olmесartan Sandoz 10 mg filmomhulde tabletten Olmесartan Sandoz 20 mg filmomhulde tabletten Olmесartan Sandoz 40 mg filmomhulde tabletten
BG	Tansidor
DE	Olmесartan – 1 A Pharma 10 mg Filmtabletten Olmесartan – 1 A Pharma 20 mg Filmtabletten Olmесartan – 1 A Pharma 40 mg Filmtabletten
EL	Olmесartan/Sandoz 10 mg επικαλυμμένα με λεπτό υμένιο δισκία Olmесartan/Sandoz 20 mg επικαλυμμένα με λεπτό υμένιο δισκία Olmесartan/Sandoz 40 mg επικαλυμμένα με λεπτό υμένιο δισκία
FR	OLMESARTAN MEDOXOMIL SANDOZ 10 mg, comprimé pelliculé OLMESARTAN MEDOXOMIL SANDOZ 20 mg, comprimé pelliculé OLMESARTAN MEDOXOMIL SANDOZ 40 mg, comprimé pelliculé
IE	Olmесartan Rowex 10mg Film-coated tablets Olmесartan Rowex 20mg Film-coated tablets Olmесartan Rowex 40mg Film-coated tablets
IT	Olmесartan Medoxomil Sandoz
NL	Olmесartan medoxomil Sandoz 10 mg, filmomhulde tabletten Olmесartan medoxomil Sandoz 20 mg, filmomhulde tabletten Olmесartan medoxomil Sandoz 40 mg, filmomhulde tabletten
PT	Olmесartan medoxomilo Sandoz Farmacêutica

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