

Package leaflet: Information for the user

Olmesartan Hydrochlorothiazide Rowex 40 mg/12.5 mg Film-coated tablets Olmesartan Hydrochlorothiazide Rowex 40 mg/25 mg Film-coated tablets

Olmesartan medoxomil/hydrochlorothiazide

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 Hydrochlorothiazide Rowex is and what it is used for
2. What you need to know before you take Olmesartan Hydrochlorothiazide Rowex
3. How to take Olmesartan Hydrochlorothiazide Rowex
4. Possible side effects
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6. Contents of the pack and other information

1. What Olmesartan Hydrochlorothiazide Rowex is and what it is used for

Olmesartan Hydrochlorothiazide Rowex contains two active substances, olmesartan medoxomil and hydrochlorothiazide, that are used to treat high blood pressure (hypertension) in adults:

- Olmesartan medoxomil is one of a group of medicines called angiotensin II-receptor antagonists. It lowers blood pressure by relaxing the blood vessels.
- Hydrochlorothiazide is one of a group of medicines called thiazide diuretics (“water tablets”). It lowers blood pressure by helping the body to get rid of extra fluid by making your kidneys produce more urine.

You will only be given Olmesartan Hydrochlorothiazide Rowex if olmesartan medoxomil alone has not adequately controlled your blood pressure. When given together, the two active substances in Olmesartan Hydrochlorothiazide Rowex help to lower blood pressure more than if either of them were given alone.

You may already be taking medicines to treat your high blood pressure, but your doctor may want you to take Olmesartan Hydrochlorothiazide Rowex to lower it more.

High blood pressure can be controlled with medicines such as Olmesartan Hydrochlorothiazide 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 Hydrochlorothiazide Rowex

Do not take Olmesartan Hydrochlorothiazide Rowex if you:

- are allergic to olmesartan medoxomil or hydrochlorothiazide, or any of the other ingredients of this medicine (listed in section 6) or to substances similar to hydrochlorothiazide (sulfonamides)
- are more than 3 months pregnant. (It is also better to avoid Olmesartan Hydrochlorothiazide Rowex in early pregnancy – see pregnancy section).
- have kidney problems
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- suffer from low potassium, low sodium, high calcium or high uric acid levels in the blood (with symptoms of gout or kidney stones) that do not get better when treated
- suffer from moderate or severe liver problems or yellowing of the skin and eyes (jaundice) or problems with drainage of the bile from the gallbladder (biliary obstruction e.g. gallstones).

If you think any of these apply to you, or you are unsure, do not take the tablets. Talk to your doctor first and follow the advice given.

Warnings and precautions

Talk to your doctor before taking Olmesartan Hydrochlorothiazide Rowex.

Before you take the tablets, **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 Hydrochlorothiazide Rowex”.

Before you take the tablets, **tell your doctor** if you have any of the following health problems:

- Kidney transplant
- Liver diseases
- Heart failure or problems with your heart valves or heart muscles
- Vomiting (being sick) or diarrhoea which is severe or it goes on for several days
- Treatment with high doses of water tablets (diuretics) or if you are on a low salt diet
- Problems with your adrenal glands (e.g. primary aldosteronism)
- Diabetes
- Lupus erythematosus (an autoimmune disease)
- Allergies or asthma
- Have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Olmesartan Hydrochlorothiazide Rowex.

Contact your doctor if you experience any of the following symptoms:

- 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.
- decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Olmesartan Hydrochlorothiazide Rowex. This can lead to permanent vision impairment, if not treated. If you previously have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

Your doctor may want to see you more often and do some tests if you have any of these conditions.

Olmesartan Hydrochlorothiazide Rowex may cause a rise in blood fat levels and uric acid levels (the cause of gout – painful swelling of the joints). Your doctor will probably want to do a blood test from time to time to check these.

It may change the levels of certain chemicals in your blood called electrolytes. Your doctor will probably want to do a blood test from time to time to check these. Signs of electrolyte changes are: thirst, dryness of the mouth, muscle pain or cramps, tired muscles, low blood pressure (hypotension), feeling weak, sluggish, tired, sleepy or restless, nausea, vomiting, less need to pass urine, a rapid heart rate. **Tell your doctor if you notice these symptoms.**

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.

If you are due to have tests for parathyroid function, you should stop taking Olmesartan Hydrochlorothiazide Rowex before these tests are carried out.

If you are a sports person, this medicine could change the results of an anti-doping test to make it positive.

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

Other medicines and Olmesartan Hydrochlorothiazide Rowex

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

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

- Other blood pressure lowering medicines (anti-hypertensives), as the effect of Olmesartan Hydrochlorothiazide Rowex 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 Hydrochlorothiazide Rowex” and “Warnings and precautions”).
- Medicines which may alter the levels of potassium in your blood if used at the same time as Olmesartan Hydrochlorothiazide Rowex. These include:
 - potassium supplements (as well as salt substitutes containing potassium)
 - water tablets (diuretics)
 - heparin (for thinning the blood)
 - laxatives
 - steroids
 - adrenocorticotrophic hormone (ACTH)
 - carbenoxolone (a medicine used to treat mouth and stomach ulcers)
 - penicillin G sodium (also called benzylpenicillin sodium, an antibiotic)
 - certain pain killers such as acetylsalicylic acid or salicylates
- Lithium (a medicine used to treat mood swings and some types of depression) used at the same time as Olmesartan Hydrochlorothiazide 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 (NSAIDs) medicines (medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis) used at the same time as Olmesartan Hydrochlorothiazide Rowex may increase the risk of kidney failure and the effect of Olmesartan Hydrochlorothiazide Rowex can be decreased by NSAIDs
- Sleeping tablets, sedatives and anti-depressant medicines, as using these medicines together with Olmesartan Hydrochlorothiazide Rowex may cause a sudden drop in blood pressure when standing up
- Certain medicines such as baclofen and tubocurarine, used to relax muscles
- Amifostine and some other medicines used to treat cancers, such as cyclophosphamide or methotrexate
- Colestyramine and colestipol, medicines for lowering blood fat levels
- Colesevelam hydrochloride, a medicine that lowers the level of cholesterol in your blood, as the effect of Olmesartan Hydrochlorothiazide Rowex may be decreased. Your doctor may advise you to take Olmesartan Hydrochlorothiazide Rowex at least 4 hours before colesevelam hydrochloride.
- Anticholinergic agents, such as atropine and biperiden
- Medicines such as thioridazine, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, sulpiride, amisulpride, pimozide, sultopride, tiapride, droperidol or haloperidol, used to treat certain psychiatric disorders
- Certain medicines such as quinidine, hydroquinidine, disopyramide, amiodarone, sotalol or digitalis, used to treat heart problems
- Medicines such as mizolastine, pentamidine, terfenadine, dofetilide, ibutilide or erythromycin injections, which may change the heart rhythm
- Oral anti-diabetic medicines, such as metformin, or insulin, used to lower blood sugar
- Beta-blockers and diazoxide, medicines used to treat high blood pressure or low blood sugar, respectively, as Olmesartan Hydrochlorothiazide Rowex can enhance their blood-sugar-increasing effect
- Methyldopa, a medicine used to treat high blood pressure
- Medicines such as noradrenaline, used to increase blood pressure and slow heart rate
- Diphemanil, used to treat a slow heartbeat or reduce sweating
- Medicines such as probenecid, sulfinpyrazone and allopurinol, used to treat gout
- Calcium supplements
- Amantadine, an anti-viral medicine

- Ciclosporin, a medicine used to stop rejection of organ transplants
- Certain antibiotics called tetracyclines or sparfloxacin
- Amphotericin, a medicine used to treat fungal infections
- Certain antacids, used to treat too much stomach acid, such as aluminium magnesium hydroxide, as the effect of Olmesartan Hydrochlorothiazide Rowex can be slightly decreased
- Cisapride, used to increase food movement in the stomach and gut
- Halofantrine, used for malaria.

Olmesartan Hydrochlorothiazide Rowex with food, drink and alcohol

Olmesartan Hydrochlorothiazide Rowex can be taken with or without food.

Take care when drinking alcohol while you are taking Olmesartan Hydrochlorothiazide Rowex, as some people feel faint or dizzy. If this happens to you, do not drink any alcohol, including wine, beer or alcopops.

Black patients

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

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 Hydrochlorothiazide 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 Hydrochlorothiazide Rowex. Olmesartan Hydrochlorothiazide Rowex is not recommended during pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if it is used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Olmesartan Hydrochlorothiazide 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.

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 Hydrochlorothiazide 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 Hydrochlorothiazide Rowex

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

The recommended dose is one Olmesartan Hydrochlorothiazide Rowex 40 mg/12.5 mg tablet a day. However, if your blood pressure is not controlled, your doctor may decide to change your dose to one Olmesartan Hydrochlorothiazide Rowex 40 mg/25 mg tablet a day.

Swallow the tablet with water. Do not chew the tablet. If possible, you should take your dose **at the same time each day**, for example at breakfast time. It is important to continue to take Olmesartan Hydrochlorothiazide Rowex until your doctor tells you to stop.

If you take more Olmesartan Hydrochlorothiazide Rowex than you should

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

If you forget to take Olmesartan Hydrochlorothiazide Rowex

If you forget to take 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 Hydrochlorothiazide Rowex

It is important to continue to take Olmesartan Hydrochlorothiazide 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.

However, the following two side effects can be serious:

- Allergic reactions that may affect the whole body, with swelling of the face, mouth and/or voice box (larynx) together with itching and rash may occur rarely. **If this happens, stop taking Olmesartan Hydrochlorothiazide Rowex and contact your doctor immediately.**
- Olmesartan Hydrochlorothiazide Rowex can cause the blood pressure to fall too low in susceptible individuals or as the result of an allergic reaction. Light-headedness or fainting may occur uncommonly. **If this happens, stop taking Olmesartan Hydrochlorothiazide Rowex, contact your doctor immediately and lie down flat.**

Olmesartan Hydrochlorothiazide Rowex is a combination of two active substances and the following information firstly gives the other side effects reported so far with the combination of olmesartan and hydrochlorothiazide (besides those already mentioned above) and, secondly, those which are known about for the separate active substances.

These are the other side effects known about so far with combination of olmesartan and hydrochlorothiazide:

If these side effects occur, they are often mild and **you do not need to stop your treatment.**

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

- dizziness

- weakness
- headache
- tiredness
- chest pain
- swelling of ankles, feet, legs, hands or arms.

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

- fluttering of the heartbeat (palpitations)
- rash
- eczema
- vertigo
- cough
- indigestion
- abdominal pain
- nausea
- vomiting
- diarrhoea
- muscle cramps and muscular pain
- pain in joints, arms and legs
- back pain
- erection difficulties in men
- blood in urine.

Some changes in blood test results have also been seen uncommonly and include:

- rise in blood fat levels
- rise in blood urea or uric acid
- rise in creatinine
- rise or decrease in blood potassium levels
- rise in blood calcium levels
- rise in blood sugar
- increase in levels of liver function.

Your doctor will know about these from a blood test and will tell you if you need to do anything.

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

- feeling unwell
- disturbances in consciousness
- skin lumps (wheals)
- acute kidney failure.

Some changes in blood test results have also been seen in rare cases and include:

- rise in blood urea nitrogen
- decrease in haemoglobin and haematocrit values.

Your doctor will know about these from a blood test and will tell you if you need to do anything.

Further side effects reported with use of olmesartan medoxomil or hydrochlorothiazide alone, but not with combination of olmesartan and hydrochlorothiazide or in a higher frequency:

Olmesartan medoxomil:

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

Bronchitis, cough, runny or stuffy nose, sore throat, abdominal pain, indigestion, diarrhoea, nausea, gastroenteritis, pain in the joints or bones, back pain, blood in urine, urinary tract infection, flu-like symptoms, pain.

Some changes in blood test results have also been seen commonly and include:

Rise in blood fat levels, rise in blood urea or uric acid, increase in levels 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, angina (pain or uncomfortable feeling in the chest; known as angina pectoris), feeling unwell, allergic skin rash, itching, exanthema (skin eruption), skin lumps (wheals).

Some changes in blood test results have also been seen uncommonly and include:

Reduced numbers of a type of blood cell, known as platelets (thrombocytopenia).

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

Impaired kidney function, lack of energy.

Some changes in blood test results have also been seen rarely and include:

Increase in blood potassium.

Hydrochlorothiazide:

Very common side effects (may affect more than 1 in 10 people):

Changes in blood results including: Increase in blood fat and uric acid levels.

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

Feeling confused, abdominal pain, stomach upset, bloated feeling, diarrhoea, nausea, vomiting, constipation, excretion of glucose into the urine.

Some changes in blood results have also been seen and include:

Increase in blood creatinine, urea, calcium and sugar levels, decrease in blood chloride, potassium, magnesium and sodium levels. Increase of serum amylase (hyperamylasaemia).

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

Decreased or loss of appetite, severe difficulty breathing, anaphylactic skin reactions (hypersensitivity reactions), worsening of pre-existing myopia, erythema, skin reactions to light, itching, purplish spots or patches on the skin due to small haemorrhages (purpura), skin lumps (wheals).

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

Swollen and sore salivary glands, decreased number of white blood cells, decreased number of blood platelets, anaemia, bone marrow damage, restlessness, feeling “down” or depressed, problems sleeping, feeling un-interested (apathy), tingling and numbness, fits (convulsions), objects you look at appearing yellow, blurred vision, dry eyes, irregular heartbeat, inflammation of the blood vessels, blood clots (thrombosis or embolism), inflammation of the lung, fluid accumulation in the lungs,

inflammation of the pancreas, jaundice, infection in the gall bladder, symptoms of lupus erythematosus such as rash, joint pains and cold hands and fingers, allergic skin reactions, peeling and blistering of the skin, non-infectious inflammation of the kidney (interstitial nephritis), fever, muscle weakness (sometimes causing impaired movement).

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

Electrolyte disturbance leading to an abnormally depleted level of chloride in the blood (hypochloraemic alkalosis), blockage in the gut (paralytic ileus).

Not known (frequency cannot be estimated from the available data):

Decrease in vision or eye pain due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma), skin and lip cancer (non-melanoma skin cancer).

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 Hydrochlorothiazide Rowex

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

This medicinal product does not require any special storage conditions.

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

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 Hydrochlorothiazide Rowex contains

The active substances are:

Olmesartan Hydrochlorothiazide Rowex 40 mg/12.5 mg Film-coated tablets

Each film-coated tablet contains 40 mg olmesartan medoxomil and 12.5 mg hydrochlorothiazide.

Olmesartan Hydrochlorothiazide Rowex 40 mg/25 mg Film-coated tablets

Each film-coated tablet contains 40 mg olmesartan medoxomil and 25 mg hydrochlorothiazide.

The other ingredients are:

Lactose monohydrate, microcrystalline cellulose, low substituted hydroxypropylcellulose, hydroxypropylcellulose, magnesium stearate, polyethylene glycol, hydroxypropyl methylcellulose, titanium dioxide (E171), iron oxide yellow (E172).

What Olmesartan Hydrochlorothiazide Rowex looks like and contents of the pack

Olmesartan Hydrochlorothiazide Rowex 40 mg/12.5 mg Film-coated tablets

Yellow film coated, oval shape, biconvex tablets debossed with 'L347' on one side and plain on other side.

Dimension: 16mm x 7.5mm

Olmesartan Hydrochlorothiazide Rowex 40 mg/25 mg Film-coated tablets

Yellow film coated, oval shape, biconvex tablets debossed with 'L348' on one side and plain on other side.

Dimension: 16mm x 7.5mm

Exhibit batch of Olmesartan Hydrochlorothiazide Rowex is packed in the following pack sizes:

Al//Al blister: 10, 14, 28, 30, 56, 60, 90 and 98 film-coated tablet

PVC/PVDC//Al blister: 10, 14, 28, 30, 56, 60, 90 and 98 film-coated tablet

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

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

Austria	Olmesartan/HCT Sandoz 40/12,5 mg Filmtabletten Olmesartan/HCT Sandoz 40/25 mg Filmtabletten
Belgium	Co-Olmesartan Sandoz 40mg/12,5 mg filmomhulde tabletten Co-Olmesartan Sandoz 40mg/25 mg filmomhulde tabletten
Bulgaria	Танзидор Н 40/12,5 mg филмирани таблетки
Germany	Olmesartan HEXAL comp 40 mg/12,5 mg Filmtabletten Olmesartan HEXAL comp 40 mg/25 mg Filmtabletten
Greece	Olmesartan + HCTZ/Sandoz, 40 mg/12,5 mg, επικαλυμμένα με λεπτό υμένιο δισκία Olmesartan+HCTZ/Sandoz, 40 mg/25 mg, επικαλυμμένα με λεπτό υμένιο δισκία
Ireland	Olmesartan Hydrochlorothiazide Rowex 40mg/12.5mg Film-coated tablets Olmesartan Hydrochlorothiazide Rowex 40mg/25mg Film-coated tablets
Italy	Olmesartan e idroclorotiazide Sandoz
Luxembourg	Co-Olmesartan Sandoz 40mg/12,5 mg comprimés pelliculés Co-Olmesartan Sandoz 40mg/25 mg comprimés pelliculés
Netherlands	Olmesartan medoxomil Hydrochlorothiazide Sandoz 40 mg/12,5 mg, filmomhulde tabletten Olmesartan medoxomil/Hydrochlorothiazide Sandoz 40 mg/ 25 mg, filmomhulde tabletten
Portugal	Olmesartan + Hidroclorotiazida Sandoz

Spain Olmesartán/Hidroclorotiazida Sandoz 40 mg/12,5 mg comprimidos recubiertos con película EFG
Olmesartán/Hidroclorotiazida Sandoz 40 mg/25 mg comprimidos recubiertos con película EFG

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