

Olmesartan Hydrochlorothiazide Rowex
20mg/12.5mg Film-coated tablets
Olmesartan Hydrochlorothiazide Rowex
20mg/25mg Film-coated tablets

Olmesartan medoxomil/hydrochlorothiazide **ROWEX**[®]

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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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):

- 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 to hydrochlorothiazide, or to any of the other ingredients in 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 severe kidney problems
 - 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 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)
 - have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

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 have any of the following health problems:

- Mild to moderate kidney problems or if you have had a recent 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.

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.

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

Talk to your doctor before taking Olmesartan Hydrochlorothiazide Rowex

- 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”

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.

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 (under 18)

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:

- 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 aspirin 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
- Other blood pressure lowering medicines (antihypertensives), as the effect of Olmesartan Hydrochlorothiazide Rowex can be increased
- 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 drugs used to treat cancers, such as cyclophosphamide or methotrexate
- Colestyramine and colestipol, medicines for lowering blood fat levels
- Colesevelam hydrochloride, a drug 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
- Drugs such as thioridazine, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, sulpiride, amisulpride, pimozide, sulpripide, 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
- Diphepanil, used to treat a slow heartbeat or reduce sweating
- Medicines such as probenecid, sulfapyrazone and allopurinol, used to treat gout
- Calcium supplements
- Amantadine, an anti-viral drug
- Ciclosporin, a medicine used to stop rejection of organ transplants
- Certain antibiotics called tetracyclines or sparflaxacin
- 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.

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”).

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 drugs 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.

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 (a type of sugar)

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 20 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 20 mg/25 mg tablet a day.

Swallow the tablet with water. 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.

