

PACKAGE LEAFLET: INFORMATION FOR THE USER

Olmesartan/Hydrochlorothiazide Teva 40 mg/12.5 mg film-coated tablets

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

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

Olmesartan/Hydrochlorothiazide 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 if olmesartan medoxomil alone has not adequately controlled your blood pressure. When given together, the two active substances in this medicine 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 to lower it more.

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

Do not take Olmesartan/Hydrochlorothiazide

If you think any of the following apply to you, or you are unsure, do not take these tablets. Talk to your doctor first and follow the advice given. In particular, do not take this medicine if you:

- are allergic to the active substances, or to any of the other ingredients of this medicine (listed in section 6)
- are allergic to substances similar to hydrochlorothiazide (sulfonamides)
- are more than 3 months pregnant (It is also better to avoid Olmesartan/Hydrochlorothiazide 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 (which may cause gout) that do not get better when treated
- suffer from moderate or severe liver problems or yellowing of the skin and eyes (jaundice)
- have problems with drainage of the bile from the gallbladder (biliary obstruction, e.g. gallstones)

Warnings and precautions

Talk to your doctor before using Olmesartan/Hydrochlorothiazide.

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”

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)
- 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.

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

This medicine may change the levels of certain chemicals in your blood called electrolytes. Your doctor may do a blood test from time to time to check this. 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, a large 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.

Medical test results

If you are due to have tests for parathyroid function, you should stop taking Olmesartan/Hydrochlorothiazide before these tests are carried out. Ask your doctor for advice before stopping treatment.

If you are a sportsman, 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 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 is not recommended for children and adolescents under the age of 18.

Other medicines and Olmesartan/Hydrochlorothiazide

Tell your doctor or pharmacist if you are using or 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 (anti-hypertensives), as the effect of Olmesartan/Hydrochlorothiazide 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” and “Warnings and precautions”).
- Medicines which may alter the levels of potassium in your blood if used at the same time as Olmesartan/Hydrochlorothiazide. 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). When used at the same time as Olmesartan/Hydrochlorothiazide 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). When used at the same time as Olmesartan/Hydrochlorothiazide may increase the risk of kidney failure. Also the effect of Olmesartan/Hydrochlorothiazide can be decreased by NSAIDs
- Sleeping tablets, sedatives and anti-depressant medicines. Using these medicines together with Olmesartan/Hydrochlorothiazide 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 such as cyclophosphamide or methotrexate (used to treat cancers)
- Colestyramine and colestipol (used for lowering blood fat levels)
- Colesevelam hydrochloride, a medicine that lowers the level of cholesterol in your blood, as the effect of Olmesartan/Hydrochlorothiazide may be decreased. Your doctor may advise you to take Olmesartan/Hydrochlorothiazide at least 4 hours before colestipol 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 (used to treat high blood pressure or low blood sugar, respectively, as Olmesartan/Hydrochlorothiazide 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 (used to stop rejection of organ transplants)
- Certain antibiotics called tetracyclines or sparfloxacin
- Amphotericin (used to treat fungal infections)
- Certain antacids such as aluminium magnesium hydroxide (used to treat too much stomach acid). The effect of Olmesartan/Hydrochlorothiazide can be slightly decreased.
- Cisapride (used to increase food movement in the stomach and gut)
- Halofantrine (used for malaria)

Olmesartan/Hydrochlorothiazide with food and drink

Olmesartan/Hydrochlorothiazide can be taken with or without food.

Take care when drinking alcohol while you are taking Olmesartan/Hydrochlorothiazide, 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 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 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. Olmesartan/Hydrochlorothiazide 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/Hydrochlorothiazide 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 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

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 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 40 mg/25 mg film-coated tablet a day.

- Swallow the tablet with water.
- Take your dose at the same time each day, for example at breakfast time.
- Take Olmesartan/Hydrochlorothiazide until your doctor tells you to stop.
- The tablet can be divided into equal doses.

If you take more Olmesartan/Hydrochlorothiazide than you should

If you take more tablets than prescribed, or if a child accidentally swallows any tablets, go to your doctor or nearest accident and emergency (A&E) department immediately. Take your medicine pack with you.

If you forget to take Olmesartan/Hydrochlorothiazide

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

It is important to continue to take Olmesartan/Hydrochlorothiazide 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 you experience the following, stop taking Olmesartan/Hydrochlorothiazide and contact your doctor immediately:

- 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.
- Olmesartan/Hydrochlorothiazide 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 lie down flat.**

Olmesartan/Hydrochlorothiazide is a combination of two active substances and the following information firstly gives the other side effects reported so far with the combination Olmesartan/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 Olmesartan/Hydrochlorothiazide:

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

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

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

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

Fluttering of the heart beat (palpitations), rash, eczema, a spinning sensation (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 (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 Olmesartan/Hydrochlorothiazide or in a higher frequency:

Olmesartan medoxomil:

Common (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 (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 (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 (may affect more than 1 in 10 people):

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

Common (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 (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 (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 uninterested (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, yellowing of the skin or whites of eyes (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 (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).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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/Hydrochlorothiazide

Do not store above 25 °C.

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 on the blister strip as 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 contains

- The active substances are olmesartan medoxomil and hydrochlorothiazide
Each film-coated tablet contains 40 mg olmesartan medoxomil and 12.5 mg hydrochlorothiazide.
Each film-coated tablet contains 40 mg olmesartan medoxomil and 25 mg hydrochlorothiazide.
- The other ingredients are:
Tablet core: Lactose monohydrate, microcrystalline cellulose, povidone (K-30), croscarmellose sodium, magnesium stearate, macrogol.
Film-coating: Hypromellose, macrogol, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172)

What Olmesartan/Hydrochlorothiazide looks like and contents of the pack

Olmesartan/Hydrochlorothiazide 40 mg/12.5 mg film-coated tablets are reddish-yellow, oval and biconvex.

Olmesartan/Hydrochlorothiazide 40 mg/25 mg film-coated tablets are pinkish, oval, biconvex and scored on one side.

They are available in blister packs of 14, 28, 30, 56 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Portugal	Olmesartan medoxomilo + Hidroclorotiazidaratiopharm
Bulgaria	Olmeta plus film-coated tablets
Estonia	Olmesartan medoxomil/HydrochlorothiazideTeva
Spain	Olmesartán/HCTZ ratiopharm comprimidos recubiertos con película EFG;
Ireland	Olmesartan Medoxomil/HydrochlorothiazideTeva Film-coated Tablets
Lithuania	Olmesartan medoxomil/HydrochlorothiazideTeva plėvele dengtos tabletės
Latvia	Olmesartan medoxomil/HydrochlorothiazideTeva apvalkotās tabletes
Slovakia	Olmesartan/HCT Teva

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