PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Olmesartan Medoxomil/Hydrochlorothiazide 20 mg/12.5 mg film-coated tablets
Olmesartan Medoxomil/Hydrochlorothiazide 20 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 Medoxomil/Hydrochlorothiazide tablets are and what they are used for

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

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

Do not take Olmesartan Medoxomil/Hydrochlorothiazide tablets

- if you are allergic to olmesartan medoxomil or hydrochlorothiazide, or any of the other ingredients of this medicine (listed in section 6) or substances similar to hydrochlorothiazide (sulfonamides)
- if you are more than 3 months pregnant (It is also better to avoid Olmesartan Medoxomil/Hydrochlorothiazide tablets in early pregnancy – see pregnancy section)
- if you have severe kidney problems
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if you 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
- if you 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)

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 or pharmacist or nurse before taking Olmesartan Medoxomil/Hydrochlorothiazide tablets.

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 Medoxomil/Hydrochlorothiazide tablets”.

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.
- if you 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 Medoxomil/Hydrochlorothiazide tablets.
- if you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Olmesartan Medoxomil/Hydrochlorothiazide tablets, seek medical attention immediately.

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 medication.
- 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 Medoxomil/Hydrochlorothiazide tablets. This can lead to permanent vision impairment, if not treated.

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

Olmesartan Medoxomil/Hydrochlorothiazide tablets 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 Medoxomil/Hydrochlorothiazide tablets before these tests are carried out.

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

Other medicines and Olmesartan Medoxomil/Hydrochlorothiazide tablets

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 Medoxomil/Hydrochlorothiazide tablets 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 Medoxomil/Hydrochlorothiazide tablets ” and “Warnings and precautions”).

- Medicines which may alter the levels of potassium in your blood if used at the same time as Olmesartan Medoxomil/Hydrochlorothiazide tablets . 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 Medoxomil/Hydrochlorothiazide tablets 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 Medoxomil/Hydrochlorothiazide tablets may increase the risk of kidney failure and the effect of Olmesartan Medoxomil/Hydrochlorothiazide tablets can be decreased by NSAIDs.
- Sleeping tablets, sedatives and anti-depressant medicines, as using these medicines together with Olmesartan Medoxomil/Hydrochlorothiazide tablets 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 Medoxomil/Hydrochlorothiazide tablets may be decreased. Your doctor may advise you to take Olmesartan Medoxomil/Hydrochlorothiazide tablets 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, 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 Medoxomil/Hydrochlorothiazide tablets 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 drug.
- 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 Medoxomil/Hydrochlorothiazide tablets can be slightly decreased.
- Cisapride, used to increase food movement in the stomach and gut.
- Halofantrine, used for malaria.

Olmesartan Medoxomil/Hydrochlorothiazide tablets with food and drink

Olmesartan Medoxomil/Hydrochlorothiazide tablets can be taken with or without food.

Take care when drinking alcohol while you are taking Olmesartan Medoxomil/Hydrochlorothiazide tablets, 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 Medoxomil/Hydrochlorothiazide tablets are somewhat less in black patients.

Pregnancy 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 Medoxomil/Hydrochlorothiazide tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Olmesartan Medoxomil/Hydrochlorothiazide tablets.
Olmesartan Medoxomil/Hydrochlorothiazide tablets are 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 Medoxomil/Hydrochlorothiazide tablets are 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 Medoxomil/Hydrochlorothiazide tablets contains lactose monohydrate

This medicine 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 Medoxomil/Hydrochlorothiazide tablets

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

The recommended dose is one Olmesartan Medoxomil/Hydrochlorothiazide tablets 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 Medoxomil/Hydrochlorothiazide tablets 20 mg/25mg 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 Medoxomil/Hydrochlorothiazide tablets until your doctor tells you to stop.

If you take more Olmesartan Medoxomil/Hydrochlorothiazide tablets 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 (A&E) department immediately and take your medicine

pack with you.

If you forget to take Olmesartan Medoxomil/Hydrochlorothiazide tablets

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 Medoxomil/Hydrochlorothiazide tablets

It is important to continue to take Olmesartan Medoxomil/Hydrochlorothiazide tablets 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 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 Medoxomil/Hydrochlorothiazide tablets and contact your doctor immediately.**

- Olmesartan Medoxomil/Hydrochlorothiazide tablets 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 Medoxomil/Hydrochlorothiazide tablets, 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 Medoxomil/Hydrochlothiazide tablets longer time ago, **contact your doctor immediately** who will evaluate your symptoms and decide on how to continue your blood pressure medication.

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

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 Olmesartan Medoxomil/Hydrochlorothiazide tablets 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).
Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).

Not known (frequency cannot be estimated from the available data):
Decrease in vision or eye pain (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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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 Medoxomil/Hydrochlorothiazide tablets

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 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 Medoxomil/Hydrochlorothiazide tablets contains
The active substances of Olmesartan Medoxomil/Hydrochlorothiazide tablets are:

Olmesartan Medoxomil/Hydrochlorothiazide tablets 20 mg/12.5 mg: Each film-coated tablet contains 20 mg olmesartan medoxomil and 12.5 mg hydrochlorothiazide.
Olmesartan Medoxomil/Hydrochlorothiazide tablets 20 mg/25 mg: Each film-coated tablet contains 20 mg olmesartan medoxomil and 25 mg hydrochlorothiazide.

The other ingredients are:

Hydroxy propyl cellulose, Lactose monohydrate, Cellulose microcrystalline, Low substituted Hydroxy propyl cellulose, Magnesium stearate, Hypromellose, Titanium dioxide (E171), Macrogol 3000, Talc, Iron oxide yellow (E172), Iron oxide red (E172)

What Olmesartan Medoxomil/Hydrochlorothiazide tablets look like and contents of the pack

Olmesartan Medoxomil/Hydrochlorothiazide tablets 20/12.5 mg are Reddish-Yellow, round, film-coated tablets; debossed with “OH1” on one side and plain on other side. Diameter approximately 8.6 mm.

Olmesartan Medoxomil/Hydrochlorothiazide tablets 20/25 mg are Pinkish, round, film-coated tablets; debossed with “OH4” on one side and plain on other side. Diameter approximately 8.6 mm.

Olmesartan Medoxomil/Hydrochlorothiazide tablets 20/12.5 mg and 20/25 mg are available in Alu-Alu blister containing 10, 14, 28, 30, 56, 84, 90, 98, 280 or 300 tablets or in Alu-Alu perforated unit dose blisters containing 10, 28, 50 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Accord Healthcare Ireland Limited,
Euro House, Euro Business Park,
Cork, T45 K857,
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Manufacturer
Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

The medicinal product is authorized in the Member States of the EEA under the following names:

Name of member state	**Name of medicinal product**
FI	Olmesartan Medoxomil/Hydrochlorothiazide Accord
IE	Olmesartan Medoxomil/Hydrochlorothiazide Accord 20/12.5 mg, 20/25 mg film-coated tablets
NL	Olmesartan Medoxomil/Hydrochloorthiazide Accord 20/12,5 mg, 20/25 mg filmomhulde tabletten
UK	Olmesartan Medoxomil/Hydrochlorothiazide 20/12.5 mg, 20/25 mg film-coated tablets

This leaflet was last approved in 10/2023.