

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

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

Olmesartan medoxomil/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 medoxomil/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 medoxomil/Hydrochlorothiazide 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**

**Do not take Olmesartan medoxomil/Hydrochlorothiazide:**

- if you are allergic to olmesartan medoxomil or to hydrochlorothiazide, or any of the other ingredients of this medicine (listed in section 6), or to substances similar to hydrochlorothiazide (sulfonamides)
- if you are more than 3 months pregnant (it is also better to avoid Olmesartan medoxomil/Hydrochlorothiazide in early pregnancy – see pregnancy section)
- if you have severe kidney problems
- 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 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 medoxomil/Hydrochlorothiazide 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 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”

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

Olmesartan medoxomil/Hydrochlorothiazide 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 before these tests are carried out.

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

You must tell your doctor if you think that you are (or might become) pregnant. Olmesartan medoxomil/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).

#### During treatment

Contact your doctor if you experience severe, persistent diarrhoea and substantial weight loss. Your doctor may evaluate your symptoms and decide on how to continue your blood pressure medication.

#### **Children and adolescents (under 18)**

Olmesartan medoxomil/Hydrochlorothiazide is not recommended for children and adolescents under the age of 18.

#### **Black patients**

As with other similar drugs the blood pressure lowering effect of Olmesartan medoxomil/Hydrochlorothiazide is somewhat less in black patients.

#### **Other medicines and Olmesartan medoxomil/Hydrochlorothiazide**

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 raise the levels of potassium in your blood if used at the same time as Olmesartan medoxomil/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)
  - amphotericin, a medicine used to treat fungal infections
  - 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 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 such as ibuprofen, aspirin and diclofenac used to relieve pain, swelling and other symptoms of inflammation, including arthritis) used at the same time as Olmesartan medoxomil/Hydrochlorothiazide may increase

the risk of kidney failure and the effect of Olmesartan medoxomil/Hydrochlorothiazide can be decreased by NSAIDs

- Other blood pressure lowering medicines (anti-hypertensives such as methyldopa ), as the effect of Olmesartan medoxomil/Hydrochlorothiazide can be increased
- Sleeping tablets, sedatives and anti-depressant medicines, as using these medicines together with Olmesartan medoxomil/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 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 medoxomil/Hydrochlorothiazide may be decreased. Your doctor may advise you to take Olmesartan medoxomil/Hydrochlorothiazide at least 4 hours before colesevelam hydrochloride.
- Anticholinergic agents, such as atropine and biperiden, used to treat irritable bowel syndrome, asthma, Parkinson's disease or other muscular problems
- Medicines such as thioridazine, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, sulphiride, amisulpride, pimozone, 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 bepridil, mizolastine, pentamidine, terfenadine, dofetilide, ibutilide and vincamine 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 can enhance their blood-sugar-increasing effect
- 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, sulfapyrazone and allopurinol, used to treat gout
- Calcium supplements
- Amantadine, an anti-viral medicine
- Cyclosporin, a medicine used to stop rejection of organ transplants
- Certain antibiotics called tetracyclines or sparfloxacin
- Certain antacids, used to treat too much stomach acid, such as aluminium magnesium hydroxide, as the effect of Olmesartan medoxomil/Hydrochlorothiazide 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 medoxomil/Hydrochlorothiazide” and “Warnings and precautions”)

### **Olmesartan medoxomil/Hydrochlorothiazide with alcohol**

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

### **Pregnancy and breast-feeding**

#### **Pregnancy**

You must tell your doctor if you think you are (or might become) pregnant or are planning to have a baby. Your doctor will normally advise you to stop taking Olmesartan medoxomil/Hydrochlorothiazide before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead. Olmesartan medoxomil/Hydrochlorothiazide is not recommended during early 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 is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

Ask your doctor or pharmacist for advice before taking any 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 unless these effects wear off. Ask your doctor for advice.

## **3. How to take Olmesartan medoxomil/Hydrochlorothiazide**

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 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 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.

### **If you take more Olmesartan medoxomil/Hydrochlorothiazide 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. Signs of an overdose may include feeling sick or sleepy, low blood pressure, causing you to feel faint or dizzy, changes to the speed or rhythm of your heart beat or excessive thirst.

### **If you forget to take Olmesartan medoxomil/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 medoxomil/Hydrochlorothiazide**

It is important to continue to take Olmesartan medoxomil/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 notice any of the following, stop taking Olmesartan medoxomil/Hydrochlorothiazide and contact your doctor or nearest hospital emergency department immediately:**

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

- Allergic reactions that may affect the whole body. Signs include sudden rash or itching, swelling of the face, lips, mouth, tongue and/or voice box (larynx) and difficulty breathing
- Sudden pain or a feeling of tightness, heaviness or pressure in the chest. These may be signs of a problem with your heart known as angina pectoris
- Severe difficulty breathing, possibly also coughing up blood, increased sweating, anxiety or pale skin. These may be signs of a problem with your lungs such as fluid or inflammation.

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

- Passing little or no urine or pain when urinating, with back pain, fever, feeling or being sick, feeling drowsy, breathless or generally unwell. These may be signs of problems with your kidneys
- Swollen and sore salivary glands
- Signs of reduced numbers of different blood cells, which may cause pale skin, feeling tired and breathless and having dark urine (reduced number of red blood cells), frequent infections with fever, chills, sore throat or mouth ulcers (reduced number of white blood cells), bleeding or bruising for longer than normal or unexpectedly, when you have not hurt yourself (reduced number of platelets)
- Fits (convulsions)
- Falling in and out of consciousness, or blacking out
- Difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration, or sudden arm or leg or foot pain (signs that a blood clot may have formed)
- Severe pain in the upper stomach, spreading to the back, possibly with feeling or being sick. These may be signs of inflammation of the pancreas
- Yellowing of the skin or of the whites of the eyes (jaundice)
- Signs of lupus erythematosus such as rash, joint pains and cold hands and fingers. This may be something you have had in the past or may be new to you
- Severe skin reactions causing painful red patches with peeling and blistering of the skin

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

- Persistent constipation with abdominal pain and vomiting (being sick), which may be signs of a blockage in the gut (paralytic ileus)

Olmesartan medoxomil/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, stop taking Olmesartan medoxomil/Hydrochlorothiazide, contact your doctor immediately and lie down flat.**

Olmesartan medoxomil/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 medoxomil 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 olmesartan medoxomil and hydrochlorothiazide taken together:**

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):

- Feeling dizzy, weak or tired
- Headache
- 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
- Spinning sensation (vertigo)
- Feeling drowsy or sleepy
- Cough
- Indigestion, abdominal pain, nausea (feeling sick), vomiting (being sick) or diarrhoea
- Muscle cramps or muscular pain
- Pain in joints, arms or legs, back pain
- Difficulties getting or maintaining an erection
- 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 substances that measure 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 generally unwell
- Pale red, itchy or painful raised bumps on the skin (wheals, or hives).

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 additional side effects reported with use of olmesartan medoxomil or hydrochlorothiazide alone, but not with Olmesartan medoxomil/Hydrochlorothiazide:**

**Olmesartan medoxomil:**

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

- Bronchitis, which causes a persistent cough, wheezing and tightness of the chest
- Runny or stuffy nose, sore throat
- Gastroenteritis, causing loose, watery stools with stomach cramps and possibly fever
- Pain in the joints or bones
- Urinary tract infection, causing pain or difficulty when urinating
- Influenza-like symptoms
- Pain.

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

Increase in levels of substances that measure muscle function.

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

- Swelling of the face
- Itching
- Sudden widespread rash with red or blistered skin, known as exanthema

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

- Impaired kidney function
- Lack of energy or enthusiasm.

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

- Severe persistent diarrhoea and substantial weight loss.

## **Hydrochlorothiazide:**

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

- Feeling confused
- Stomach upset, bloated feeling, wind, constipation
- Excretion of glucose into the urine, which may cause your urine to smell sweet and will show in a urine test.

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

Decrease in blood chloride magnesium or sodium levels, increase of serum amylase (hyperamylasaemia).

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

- Decreased or loss of appetite
- Worsening of pre-existing short-sightedness
- Red patches on the skin (erythema) or skin reactions to light
- Purplish spots or patches under the skin due to small areas of bleeding (purpura).

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

- Feeling restless, 'down' or depressed, problems sleeping, feeling uninterested (apathy)
- Numbness or tingling ('pins and needles')
- Objects you look at appearing yellow, blurred vision, dry eyes
- Irregular heartbeat
- Inflammation of the blood vessels, which causes a rash and sometimes blistering of the skin
- Infection in the gall bladder, which causes severe pain and tenderness in the upper abdomen, with a fever
- Muscle weakness (sometimes causing difficulties with movement).

### **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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@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**

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

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton and on the blister strip 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 medoxomil/Hydrochlorothiazide contains**

The active substances are:

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

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

The other ingredients are:

(tablet core) croscarmellose sodium, mannitol, microcrystalline cellulose, low-substituted hydroxypropyl cellulose, colloidal anhydrous silica, magnesium stearate, sodium laurilsulfate and (tablet coating) hypromellose, titanium dioxide (E171), macrogol, talc.

Olmesartan medoxomil/Hydrochlorothiazide 20 mg/25 mg: (tablet coating) also contains iron oxide yellow (E172), iron oxide red (E172).

### **What Olmesartan medoxomil/Hydrochlorothiazide looks like and contents of the pack**

Olmesartan medoxomil/Hydrochlorothiazide 20 mg/12.5 mg film-coated tablets are white, film coated, round, biconvex beveled edge tablets marked with 'M' on one side of the tablet and 'H4' on the other side.

Olmesartan medoxomil/Hydrochlorothiazide 20 mg/25 mg film-coated tablet are yellow, film coated, oblong, biconvex beveled edge tablets marked with 'M' on one side of the tablet and 'H5' on the other side.

Olmesartan medoxomil/Hydrochlorothiazide film-coated tablets are available in blister packs of 14, 28, 30, 56, 90, 98 and calendar pack of 28 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

McDermott Laboratories Ltd., t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

### **Manufacturer**

McDermott Laboratories Ltd., t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Generics [UK] Limited, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Mylan Hungary Kft., H-2900, Komárom, Mylan utca 1, Hungary

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

Greece	Olmesartan/HCTZ Mylan 20 mg/12.5 mg, 20 mg/25 mg film-coated tablets
Ireland	Olmesartan medoxomil/Hydrochlorothiazide 20 mg/12.5 mg, 20 mg/25 mg film-coated tablets
Portugal	Olmesartan medoxomilo + Hidroclorotiazida Mylan
Spain	Olmesartan/Hidroclorotiazida Mylan 20 mg/12.5 mg, 20 mg/25 mg comprimidos recubiertos con película EFG

**This leaflet was last revised in 01/2016**