Package leaflet: Information for the user

/…/ 20 mg/12.5 mg film-coated tablets
/…/ 20 mg/25 mg film-coated tablets
/…/ 40 mg/12.5 mg film-coated tablets
/…/ 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 /…/ is and what it is used for
2. What you need to know before you take /…/
3. How to take /…/
4. Possible side effects
5. How to store /…/
6. Contents of the pack and other information

1. What /…/ is and what it is used for

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

High blood pressure can be controlled with medicines such as /…/ 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 /…/

Do not take /…/:

- 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 /…/ in early pregnancy – see pregnancy section)
- 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 have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

[Applies only for 20 mg/12.5 mg and 20 mg/25 mg]
- if you have severe kidney problems
- 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)

[Applies only for 40 mg/12.5 mg and 40 mg/25 mg]
- if you have kidney problems
- if you 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 /…/
If you have any of the following health problems:
- Kidney problems or kidney transplant
- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys)
- 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

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

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 /…/”

/…/ 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 /…/ 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. /…/ 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
/…/ is not recommended for children and adolescents under the age of 18.

Other medicines and /…/
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may need to change your dose and/or to take other precautions:

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 /…/. 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 /…/ 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 /…/ may increase the risk of kidney failure and the effect of /…/ can be decreased by NSAIDs
- Other blood pressure lowering medicines (anti-hypertensives), as the effect of /…/ can be increased
- Sleeping tablets, sedatives and anti-depressant medicines, as using these medicines together with /…/ 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
- 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 /…/ 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 /…/ can be slightly decreased
- Cisapride, used to increase food movement in the stomach and gut
- Halofantrine, used for malaria.
- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take /…/ and "Warnings and precautions")

/…/ with food, drink and alcohol
/…/ can be taken with or without food.

Take care when drinking alcohol while you are taking /…/, 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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask you doctor for advice before taking this medicine.

Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking /…/ before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of /…/. /…/ 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.

Breastfeeding
Tell your doctor if you are breast-feeding or about to start breastfeeding. /…/ is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed.

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.

Black patients
As with other similar drugs the blood pressure lowering effect of /…/ is somewhat less in black patients.

[Applies only for 20 mg/12.5 mg and 40 mg/12.5 mg]
/…/ contains lactose and sunset yellow
Lactose: if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product
Sunset yellow: May cause allergic reactions
[Applies only for 20 mg/25 mg and 40 mg/25 mg]
/…/ contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

3. How to take /…/

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

[Applies only for 20 mg/12.5 mg and 20 mg/25 mg]
The recommended dose is one /…/ 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 /…/ 20 mg/25 mg tablet a day.
[Applies only for 40 mg/12.5 mg and 40 mg/25 mg]
The recommended dose is one /…/ 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 /…/ 40 mg/25 mg tablet a day.

Swallow the tablet whole with water. Do not bite, chew or break them. 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 /…/ until your doctor tells you to stop.

If you take more /…/ 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 /…/
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 /…/
It is important to continue to take /…/ 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 /…/ and contact your doctor immediately.**

- /…/ 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 /…/, contact your doctor immediately and lie down flat.**

/…/ 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 medoxomil and hydrochlorothiazide (besides those already mentioned above) and, secondly, those which are known about for the separate active substances.

To give you an idea of how many patients might get side effects, they have been listed as common, uncommon, rare and very rare. These mean the following:

Other side effects include:

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):
Sleepiness, fluttering of the heart beat (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 and 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 /…/ 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).

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store /…/

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 or 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 /…/ contains

- The active substances are olmesartan medoxomil and hydrochlorothiazide. Each tablet contains 20 mg olmesartan medoxomil and 12.5 mg hydrochlorothiazide.
- The active substances are olmesartan medoxomil and hydrochlorothiazide. Each tablet contains 20 mg olmesartan medoxomil and 25 mg hydrochlorothiazide.
- The active substances are olmesartan medoxomil and hydrochlorothiazide. Each tablet contains 40 mg olmesartan medoxomil and 12.5 mg hydrochlorothiazide.

- The active substances are olmesartan medoxomil and hydrochlorothiazide. Each tablet contains 40 mg olmesartan medoxomil and 25 mg hydrochlorothiazide.
- The other ingredients are:
  Tablet core: Lactose monohydrate, low substituted hydroxy propylcellulose, hydroxypropylcellulose, cellulose, microcrystalline type 102, magnesium stearate
  Tablet coating:
  [Applies only for 20 mg/12.5 mg and 40 mg/12.5 mg] Opadry II Orange 33G23991 containing: Hypromellose 6cP, titanium dioxide (E171), lactose monohydrate, macrogol 3350, triacetin (E1518), iron oxide yellow (E172), iron oxide red (E172), sunset yellow FCF aluminium lake (E110)
  [Applies only for 20 mg/25 mg and 40 mg/25 mg] Opadry II Pink 33G34149 containing: Hypromellose 6cP, titanium dioxide (E171), lactose monohydrate, macrogol 3350, triacetin (E1518), iron oxide yellow (E172), iron oxide red (E172)

What /…/ looks like and contents of the pack

/.../ 20 mg/12.5 mg film-coated tablets are orange, round, biconvex, 8.5 mm in diameter and with OH 21 debossed on one side
/.../ 20 mg/25 mg film-coated tablets are pink, round, biconvex, 8.5 mm in diameter and with OH 22 debossed on one side
/.../ 40 mg/12.5 mg film-coated tablets are orange, oval, biconvex, 15 x 7 mm and with OH 41 debossed on one side
/.../ 40 mg/25 mg film-coated tablets are pink, oval, biconvex, 15 x 7 mm and with OH 42 debossed on one side

Pack sizes
Blister packs (Al-Al): 14, 28, 30, 90, 98, 100 film-coated tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

[To be completed nationally]

This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.

[To be completed nationally]