PACKAGE LEAFLET: INFORMATION FOR THE USER

Olmesartan Medoxomil 10 mg film coated tablets
Olmesartan Medoxomil 20 mg film coated tablets
Olmesartan Medoxomil 40 mg film coated tablets
olmesartan medoxomil

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 sign of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet:

1. What Olmesartan Medoxomil is and what it is used for

Olmesartan Medoxomil belongs to a group of medicines called angiotensin-II receptor antagonists. They lower blood pressure by relaxing the blood vessels.

Olmesartan Medoxomil are used for the treatment of high blood pressure (also known as 'hypertension') in adults and in children and adolescents aged 6 to less than 18 years. High blood pressure can damage blood vessels in organs such as the heart, kidneys, brain and eyes. In some cases this may lead to a heart attack, heart or kidney failure, stroke or blindness. Usually high blood pressure has no symptoms. It is important to have your blood pressure checked to prevent damage occurring.

High blood pressure can be controlled with medicines such as Olmesartan Medoxomil. 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

Do not take Olmesartan Medoxomil
- if you are allergic (hypersensitive) to Olmesartan Medoxomil or to any other of the ingredients of this medicine (listed in section 6).
- if you are more than 3 months pregnant. (It is also better to avoid Olmesartan Medoxomil in early pregnancy - see pregnancy section.)
- if you suffer from 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.

Warnings and precautions
Talk to your doctor before using Olmesartan Medoxomil.

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 ".

Tell your doctor if you have any of the following health problems:
- Kidney problems
- Liver disease
- Heart failure or problems with your heart valves or heart muscle
- Severe vomiting, diarrhoea, treatment with high doses of water tablets (diuretics) or if you are on a low salt diet
- Increased levels of potassium in your blood
- Problems with your adrenal glands.

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.

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Olmesartan Medoxomil. Your doctor will decide on further treatment. Do not stop taking Olmesartan Medoxomil on your own.

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.

You must tell your doctor if you think you are (or might become) pregnant. Olmesartan Medoxomil 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 Medoxomil has been studied in children and adolescents. For more information, talk to your doctor. Olmesartan Medoxomil is not recommended for children from 1 year to less than 6 years and should not be used in children under the age of 1 year as no experience is available.

Other medicines and Olmesartan Medoxomil
Please 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, as the effect of Olmesartan Medoxomil 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" and "Warnings and precautions").
- Potassium supplements, a salt substitute which contains potassium, water tablets (diuretics) or heparin (for thinning the blood). Using these medicines at the same time as Olmesartan Medoxomil may raise the levels of potassium in your blood.
- Lithium (a medicine used to treat mood swings and some types of depression) used at the same time as Olmesartan Medoxomil 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 may increase the risk of kidney failure and the effect of Olmesartan Medoxomil can be decreased by NSAIDs.
- Colesevelam hydrochloride, a drug that lowers the level of cholesterol in your blood, as the effect of Olmesartan Medoxomil Tablets may be decreased. Your doctor may advise you to take Olmesartan Medoxomil Tablets at least 4 hours before colesevelam hydrochloride.
- Certain antacids (indigestion remedies), as the effect of Olmesartan Medoxomil can be slightly decreased.

Older people
If you are over 65 years of age and your doctor decides to increase your dose of Olmesartan Medoxomil to 40 mg daily, then you need to have your blood pressure regularly checked by your doctor to make sure that your blood pressure does not become too low.

Black patients
As with other similar drugs the blood pressure lowering effect of Olmesartan Medoxomil Tablets is somewhat less in black patients.

Olmesartan Medoxomil with food and drink
Olmesartan Medoxomil can be taken with or without food.

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 Medoxomil 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 Tablets. Olmesartan Medoxomil Tablets 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 Medoxomil Tablets is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.
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 until the symptoms wear off. Ask your doctor for advice.

Olmesartan Medoxomil contains lactose

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 medicinal product.

3. How to take Olmesartan Medoxomil

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

The recommended starting dose is one 10 mg tablet once a day. However, if your blood pressure is not controlled, your doctor may decide to change your dose up to 20 or 40 mg once a day, or prescribe additional medicines.

In patients with mild to moderate kidney disease, your dose will not be higher than 20 mg once a day.

The tablets can be taken with or without food. Swallow the tablets with a sufficient amount of water (e.g. one glass). If possible, take your daily dose at the same time each day, for example at breakfast
time.

Children and adolescents from 6 to less than18 years of age:
The recommended starting dose is 10 mg once daily. If the patient's blood pressure is not adequately controlled, the doctor may decide to change the dose up to 20 or 40 mg once a day. In children who weigh less than 35 kg, the dose will not be higher than 20 mg once a day.

If you take more Olmesartan Medoxomil than you should
If you take more tablets than you should or if a child accidentally swallows some, go to your doctor or nearest emergency department immediately and take your medicine pack with you.

If you forget to take Olmesartan Medoxomil
If you forget 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
It is important to continue to take Olmesartan Medoxomil unless your doctor tells you to stop.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If they do occur, they are often mild and do not require treatment to be stopped.

Although not many people may get them, the following side effects can be serious:

On rare occasions (may affect up to 1 in 1,000 people) the following allergic reactions that may affect the whole body have been reported:
Swelling of the face, mouth and/or larynx (voice box) together with itching and rash may occur during treatment with Olmesartan Medoxomil. **If this happens stop taking Olmesartan Medoxomil Tablets and contact your doctor immediately.**

Rarely (but slightly more often in older people) Olmesartan Medoxomil can cause the blood pressure to fall too low in susceptible individuals or as the result of an allergic reaction. This

could cause severe light-headedness or fainting. **If this occurs stop taking Olmesartan Medoxomil, contact your doctor immediately and lie down flat.**

These are the other side effects known about so far with Olmesartan Medoxomil:

Common side effects (may affect up to 1 in 10 people):
Dizziness, headache, nausea, indigestion, diarrhoea, stomach ache, gastroenteritis, tiredness, sore throat, runny or stuffy nose, bronchitis, flu-like symptoms, cough, pain, pain in the chest, back, bones or joints, infection of the urinary tract, swelling of ankles, feet, legs, hands, or arms, blood in the urine.

Some changes in blood test results have also been seen and include the following:
increased fat levels (hypertriglyceridaemia), increased uric acid levels (hyperuricaemia), rise in blood urea, increases in tests 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, vertigo, vomiting, weakness, feeling unwell, muscular pain, skin rash, allergic skin rash, itching, exanthema (skin eruption), skin lumps (wheals), angina (pain or uncomfortable feeling in the chest).

In blood tests a reduction of the numbers of a type of blood cell, known as platelets has been seen (thrombocytopenia).

Rare side effects (may affect up to 1 in 1,000 people):
Lack of energy, muscle cramps, impaired kidney function, kidney failure.

Some changes in blood test results have also been seen. These include increased potassium levels (hyperkalaemia) and increased levels of compounds related to kidney function.

Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.

Not known: frequency cannot be estimated from the available data:
If you experience yellowing of the whites of the eyes, dark urine, itching of the skin, even if you started therapy with Olmesartan Medoxomil longer time ago, **contact your doctor immediately** who will evaluate your symptoms and decide on how to continue your blood pressure medication.

Additional side effects in children and adolescents:
In children, side effects are similar to those reported in adults. However, dizziness and headache are seen more often in children, and nose bleeding is a common side effect seen in children only.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
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

- 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 after "EXP". The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- 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 contains
The active ingredient is Olmesartan Medoxomil**.**
Each film-coated tablet contains 10 mg Olmesartan Medoxomil.
Each film-coated tablet contains 20 mg Olmesartan Medoxomil.
Each film-coated tablet contains 40 mg Olmesartan Medoxomil.

Other ingredients are:
Cellulose microcrystalline, lactose monohydrate, hydroxypropylcellulose, low substituted hydroxypropylcellulose, magnesium stearate, titanium dioxide (E171), talc and hypromellose.

What Olmesartan Medoxomil looks like and contents of the pack

Olmesartan Medoxomil 10 mg film-coated tablets are White to off-white, round, biconvex, film coated tablets, debossed with "IO2" on one side and plain on other side.

Olmesartan Medoxomil 20 mg film-coated tablets are White to off-white, round, biconvex, film coated tablets, debossed with "IO3" on one side and plain on other side.

Olmesartan Medoxomil 40 mg film-coated tablets are White to off-white, oval, biconvex, film coated tablets, debossed with "IO4" on one side and plain on other side.

Olmesartan Medoxomil are available in packs of 14, 28, 30, 56, 84, 90, 98 and 280 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer

Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park, Paola, PLA 3000
Malta

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

The medicine is authorized in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the Member State	**Name of the medicine**
Germany	Olmesartan Medoxomil Accord 10mg/20mg/40mg Filmtabletten
Estonia	Olmesartan Medoxomil Accord
Finland	Olmesartan Medoxomil Accord 10mg/20mg/40mg tabletti, kalvopäällysteinen
Ireland	Olmesartan Medoxomil 10mg/20mg/40mg film coated tablets
Italy	Olmesartan Medoxomil Accord
Lithuania	Olmesartan medoxomil Accord 10mg/20mg/40mg plėvele dengtos tabletės
Latvia	Olmesartan Medoxomil Accord 10mg/20mg/40mg apvalkotās tabletes
The Netherlands	Olmesartan Medoxomil Accord 10mg/20mg/40mg filmomhulde tabletten
Norway	Olmesartan Medoxomil Accord 10mg/20mg/40mg tabletter, filmdrasjerte
United Kingdom (Northern Ireland)	Olmesartan Medoxomil 10mg/20mg/40mg film coated tablets

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