PACKAGE LEAFLET: INFORMATION FOR THE USER

Omesar® 10mg film-coated tablets

(olmesartan medoxomil)

Your medicine is available using the above name but will be referred to as Omesar throughout this leaflet.

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. Do not pass it 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 Omesar is and what it is used for
2. What you need to know before you take Omesar
3. How to take Omesar
4. Possible side effects
5. How to store Omesar
6. Contents of the pack and other information

1. What Omesar is and what it is used for

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

Omesar is used for the treatment of high blood pressure (also known as 'hypertension'). 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 Omesar 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 Omesar

Do not take Omesar:

- if you are allergic to olmesartan medoxomil or any of the other ingredients of this medicine (listed in section 6)
- if you are more than 3 months pregnant. (It is also better to avoid Omesar 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 taking Omesar.

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 Omesar"

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.

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. Omesar 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

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

Other medicines and Omesar:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines:

- Other blood pressure lowering medicines, as the effect of Omesar 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 Omesar" 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 Omesar 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 Omesar 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 Omesar may increase the risk of kidney failure and the effect of Omesar can be decreased by NSAIDs.
- Colesevelam hydrochloride, a drug that lowers the level of cholesterol in your blood, as the effect of Omesar may be decreased. Your doctor may advise you to take Omesar at least 4 hours before colesevelam hydrochloride.
- Certain antacids (indigestion remedies), as the effect of Omesar 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 Omesar is somewhat less in black patients.

Omesar with food and drink:

Omesar 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 Omesar before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Omesar. Omesar 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. Omesar 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.

Omesar contains lactose monohydrate

This medicine contains lactose monohydrate (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 Omesar

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist 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**.**

If you take more Omesar 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 Omesar
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 tablet.

If you stop taking Omesar
It is important to continue to take Omesar unless your doctor tells you to stop.

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

There is a memory aid on the blister packs for the daily intake.

The translations of the days of the week are as follows:

ΔΕ	ΤΡ	ΤΕ	ΠΕ	ΠΑ	ΣΑ	ΚΥ
Mon	Tue	Wed	Thu	Fri	Sat	Sun

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 two 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 Omesar. **If this happens stop taking Omesar and contact your doctor immediately.**

Rarely (but slightly more often in older people) Omesar 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 Omesar, contact your doctor immediately and lie down flat.**

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

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), 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.

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 Omesar

- Keep out of the sight and reach of children.
- Do not use Omesar after the expiry date (Exp) which is stated on the carton. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage condition.
- If your doctor decides to stop the treatment, return any leftover medicine to the pharmacist. Only keep it if your doctor tells you to.
- If your medicine appears to be discoloured or show any other signs of deterioration, please return to your pharmacist who will advise you further.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Omesar contains
The active substance is olmesartan medoxomil.
Each film-coated tablet contains 10mg of olmesartan medoxomil.

The other ingredients are:
Tablet core: microcrystalline cellulose, lactose monohydrate, hydroxypropylcellulose, low substituted hydroxypropylcellulose and magnesium stearate
Tablet coating: titanium dioxide (E171), talc and hypromellose.

What Omesar looks like and contents of the pack
Omesar are white, circular, film-coated tablets with C13 embossed on one side.

Omesar is available in blister packs of 28 tablets.

Manufacturer
Manufactured by: Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276 Pfaffenhofen, Germany.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Santry, Dublin 9

PPA No: 1151/154/2

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Austria: Mencord
Belgium: Belsar
Cyprus: Olartan
Czech Republic: Sarten
Denmark: Benetor
Germany: Votum
Greece: Olartan
Finland: Benetor
France: Alteis
Iceland: Benetor
Ireland: Omesar
Italy: Olpress
Luxembourg: Belsar
Malta: Omesar
Norway: Benetor
Poland: Revival
Portugal: Olsar
Slovenia: Tensiol
Spain: Ixia