

## **Package leaflet: Information for the user**

### **Olmesartan Medoxomil Clonmel 10mg film-coated tablets Olmesartan Medoxomil Clonmel 20mg film-coated tablets Olmesartan Medoxomil Clonmel 40mg 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 signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, 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 Clonmel is and what it is used for
2. What you need to know before you take Olmesartan Medoxomil Clonmel
3. How to take Olmesartan Medoxomil Clonmel
4. Possible side effects
5. How to store Olmesartan Medoxomil Clonmel
6. Contents of the pack and other information

#### **1. What Olmesartan Medoxomil Clonmel is and what it is used for**

Olmesartan Medoxomil Clonmel contains the active ingredient **olmesartan** which belongs to a group of medicines called angiotensin-II receptor antagonists. They lower blood pressure by relaxing the blood vessels.

Olmesartan Medoxomil Clonmel 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 Olmesartan Medoxomil Clonmel 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 Clonmel**

##### **DO NOT take Olmesartan Medoxomil Clonmel:**

- 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 Olmesartan Medoxomil Clonmel tablets 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 or pharmacist before taking Olmesartan Medoxomil Clonmel**

- 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 Clonmel”

**Tell your doctor** if you:

- have kidney problems
- have liver disease
- have heart failure or problems with your heart valves or heart muscle
- suffer from severe vomiting
- have diarrhoea
- are on treatment with high doses of water tablets (diuretics)
- are on a low salt diet
- have increased levels of potassium in your blood
- have 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 Clonmel. Your doctor will decide on further treatment. Do not stop taking Olmesartan Medoxomil Clonmel on your own.

As with any medicine that 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 Clonmel 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 Clonmel is not recommended for children and adolescents under the age of 18.

### **Other medicines and Olmesartan Medoxomil Clonmel**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine:

- other blood pressure lowering medicines, as the effect of Olmesartan Medoxomil Clonmel 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 Clonmel” 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 Clonmel 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 Clonmel 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) used to relieve pain, swelling and other symptoms of inflammation, including arthritis. If used at the same time as Olmesartan Medoxomil Clonmel you may have an increased risk of kidney failure and in addition, the effect of Olmesartan Medoxomil Clonmel can be decreased by NSAIDs.
- colestesvelam hydrochloride, a drug that lowers the level of cholesterol in your blood, as the effect of Olmesartan Medoxomil Clonmel may be decreased. Your doctor may advise you to take

Olmesartan Medoxomil Clonmel at least 4 hours before colesevelam hydrochloride.

- certain antacids (indigestion remedies), as the effect of Olmesartan Medoxomil Clonmel can be slightly decreased.

### **Elderly**

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

### **Black patients**

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

### **Olmesartan Medoxomil Clonmel with food**

Olmesartan Medoxomil Clonmel 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 Clonmel 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 Clonmel. Olmesartan Medoxomil Clonmel 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 Clonmel 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.

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 Clonmel 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 medicine.

## **3. How to take Olmesartan Medoxomil Clonmel**

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

### **Dosage**

The recommended starting dose is 10 mg once a day. However, if your blood pressure is not controlled, your doctor may decide to change your dose 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.

### **Method of administration**

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

**If you take more Olmesartan Medoxomil Clonmel 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 Clonmel**

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 Olmesartan Medoxomil Clonmel**

It is important to continue to take Olmesartan Medoxomil Clonmel 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 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 Clonmel. **If this happens stop taking Olmesartan Medoxomil Clonmel and contact your doctor immediately.**

Rarely (but slightly more often in older people) Olmesartan Medoxomil Clonmel 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 Clonmel, 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 Clonmel longer time ago, **contact your doctor immediately** who will evaluate your symptoms and decide on how to continue your blood pressure medication.

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

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

- dizziness, tiredness
- headache
- nausea, indigestion, diarrhoea, stomach ache, gastroenteritis
- 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, blood in the urine
- swelling of ankles, feet, legs, hands, or arms

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, feeling unwell
- weakness
- 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
- intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea

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.

**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, 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](http://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 Clonmel**

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

Olmesartan Medoxomil Clonmel 10 mg film-coated tablets:

This medicinal product does not require any special storage conditions.

Olmesartan Medoxomil Clonmel 20 mg film-coated tablets:

This medicinal product does not require any special storage conditions.

Olmesartan Medoxomil Clonmel 40 mg film-coated tablets:

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the box and on the blister strip ("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 Clonmel contains**

The active substance is olmesartan medoxomil.

Each film-coated tablet contains 10 mg, 20 mg or 40 mg olmesartan medoxomil.

The other ingredients are: lactose monohydrate, microcrystalline cellulose, crospovidone, silica, magnesium stearate, hypromellose, polyethylene glycol, titanium dioxide.

**What Olmesartan Medoxomil Clonmel looks like and contents of the pack**

Olmesartan Medoxomil Clonmel 10 mg film-coated tablets are white, round, biconvex film-coated tablets with a diameter of 6 mm.

The film-coated tablets are available in blister packs of 10, 10 (sample), 14, 28, 30, 56, 60, 90, 98, 100 film-coated tablets.

Olmesartan Medoxomil Clonmel 20 mg film-coated tablets are white, round, biconvex film-coated tablets with a diameter of 8 mm.

The film-coated tablets are available in blister packs of 10, 14, 14 (sample), 28, 28 (sample), 30, 56, 60, 90, 98, 100 film-coated tablets.

Olmesartan Medoxomil Clonmel 40 mg film-coated tablets are white, oval, biconvex film-coated tablets with a length of 15 mm and a width of 6 mm.

The film-coated tablets are available in blister packs of 10, 14, 28, 30, 56, 60, 90, 98, 100 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

**Manufacturer**

STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel, Germany

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

STADA M&D SRL, Str. Trascăului, nr 10, RO-401135, Turda, Romania

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

BE	Olmesartan EG 10, 20, 40 mg filmomhulde tabletten
DE	Olmesartan AL 10, 20, 40 mg Filmtabletten
ES	Olmesartan STADA 10, 20, 40 mg comprimidos recubiertos con película EFG
FI	Olmesartan medoxomil STADA 10, 20, 40 mg kalvopäällysteiset tabletit
IE	Olmesartan Medoxomil Clonmel 10, 20, 40 mg film-coated tablets
IT	Olmesartan Medoxomil EG
LU	Olmesartan EG 10, 20, 40 mg comprimés pelliculés
PT	Olmesartan medoxomilo Ciclum

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