

## Package leaflet: Information for the user

### **Irbesartan Clonmel 75mg Film-coated Tablets** **Irbesartan Clonmel 150mg Film-coated Tablets** **Irbesartan Clonmel 300mg Film-coated Tablets**

#### Irbesartan

**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 symptoms 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 Irbesartan Clonmel is and what it is used for
2. What you need to know before you take Irbesartan Clonmel
3. How to take Irbesartan Clonmel
4. Possible side effects
5. How to store Irbesartan Clonmel
6. Contents of the pack and other information

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

Irbesartan Clonmel belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels causing them to tighten. This results in an increase in blood pressure. Irbesartan Clonmel prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower. Irbesartan Clonmel slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

#### **Irbesartan Clonmel is used to:**

- treat high blood pressure (essential hypertension)
- protect the kidney in patients with high blood pressure, type 2 diabetes and laboratory evidence of impaired kidney function.

#### **2. What you need to know before you take Irbesartan Clonmel**

##### **DO NOT take Irbesartan Clonmel**

- if you are allergic to irbesartan or any other ingredients of this medicine (listed in section 6).
- if you are **more than 3 months pregnant**. (It is also better to avoid Irbesartan Clonmel in early pregnancy– see pregnancy section)
- 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 Irbesartan Clonmel or if any of the following apply to you:

- if you get **excessive vomiting or diarrhoea**
- if you suffer from **kidney problems**
- if you suffer from **heart problems**
- if you are **going to have an operation** (surgery) or **be given anaesthetics**
- 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 Irbesartan Clonmel”

- You must tell your doctor if you think you are (or might become) pregnant. Irbesartan 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**

This medicinal product should not be used in children and adolescents because the safety and efficacy has not yet been fully established.

### **Other medicines and Irbesartan Clonmel**

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:

If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Irbesartan Clonmel” and “Warnings and precautions”).

### **You may need to have blood checks if you take:**

- potassium supplements
- salt substitutes containing potassium
- potassium-sparing medicines (such as certain diuretics)
- medicines containing lithium

If you take certain painkillers, called non-steroidal anti-inflammatory drugs, the effect of irbesartan may be reduced.

### **Irbesartan Clonmel with food and drink**

Irbesartan Clonmel can be taken with or without food.

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

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.

#### Pregnancy

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

Irbesartan 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.

### **Driving and using machines**

No studies on the effects on the ability to drive and use machines have been performed. Irbesartan Clonmel is unlikely to affect your ability to drive or use machines. However, occasionally dizziness

or weariness may occur during treatment of high blood pressure. If you experience these, talk to your doctor before attempting to drive or use machines.

### **Irbesartan Clonmel contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine.

### **3. How to take Irbesartan Clonmel**

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

#### **Method of administration**

Irbesartan Clonmel is for **oral use**. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take Irbesartan Clonmel with or without food. Try to take your daily dose at about the same time each day. It is important that you continue to take Irbesartan Clonmel until your doctor tells you otherwise.

- **Patients with high blood pressure**

#### **Irbesartan Clonmel 75 mg**

The recommended dose is 150 mg once a day (two tablets a day). The dose may later be increased to 300 mg (four tablets a day) once daily depending on blood pressure response.

#### **Irbesartan Clonmel 150 mg**

The recommended dose is 150 mg once a day (one tablet a day). The dose may later be increased to 300 mg (two tablets a day) once daily depending on blood pressure response.

#### **Irbesartan Clonmel 300 mg**

The recommended dose is 150 mg once a day (for this dose other strengths of Irbesartan Clonmel are available). The dose may later be increased to 300 mg (one tablet a day) once daily depending on blood pressure response.

- **Patients with high blood pressure and type 2 diabetes with kidney disease**

#### **Irbesartan Clonmel 75 mg**

In patients with high blood pressure and type 2 diabetes, 300 mg (four tablets a day) once daily is the recommended maintenance dose for the treatment of associated kidney disease.

#### **Irbesartan Clonmel 150 mg**

In patients with high blood pressure and type 2 diabetes, 300 mg (two tablets a day) once daily is the recommended maintenance dose for the treatment of associated kidney disease.

#### **Irbesartan Clonmel 300 mg**

In patients with high blood pressure and type 2 diabetes, 300 mg (one tablet a day) once daily is the recommended maintenance dose for the treatment of associated kidney disease.

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those on **haemodialysis**, or those **over the age of 75 years**.

The maximal blood pressure lowering effect should be reached 4-6 weeks after beginning treatment.

### **If you take more Irbesartan Clonmel than you should**

If you accidentally take too many tablets, contact your doctor immediately.

### **Children should not take Irbesartan Clonmel.**

Irbesartan Clonmel should not be given to children under 18 years of age. If a child swallows some tablets, contact your doctor immediately.

**If you forget to take Irbesartan Clonmel**

If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

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.

Some of these effects may be serious and may require medical attention.

As with similar medicines, rare cases of allergic skin reactions (rash, urticaria), as well as localised swelling of the face, lips and/or tongue have been reported in patients taking irbesartan. If you get any of these symptoms or get short of breath, **stop taking Irbesartan Clonmel and contact your doctor immediately.**

Irbesartan Clonmel can cause the following side effects:

**Very common (may affect more than 1 in 10 people):**

- if you suffer from high blood pressure and type 2 diabetes with kidney disease, blood tests may show an increased level of potassium.

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

- dizziness, feeling sick/vomiting, fatigue and blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatinine kinase enzyme). In patients with high blood pressure and type 2 diabetes with kidney disease, dizziness when getting up from a lying or sitting position, low blood pressure when getting up from a lying or sitting position, pain in joints or muscles and decreased levels of a protein in the red blood cells (haemoglobin) were also reported.

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

- heart rate increased, flushing, cough, diarrhoea, indigestion/heartburn, sexual dysfunction (problems with sexual performance), chest pain, yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice).

**Not known (frequency cannot be estimated from the available data):**

- headache, taste disturbance, ringing in the ears, a feeling of dizziness or “spinning” (vertigo), muscle cramps, pain in joints and muscles, abnormal liver function, increased blood potassium levels, impaired kidney function, inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis) and reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)

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](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 Irbesartan Clonmel**

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 after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature 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 to protect the environment.

## **6. Contents of the pack and other information**

### **What Irbesartan Clonmel contains**

The active substance is irbesartan.

One Irbesartan Clonmel 75 mg film-coated tablet contains 75 mg irbesartan.

One Irbesartan Clonmel 150 mg film-coated tablet contains 150 mg irbesartan.

One Irbesartan Clonmel 300 mg film-coated tablet contains 300 mg irbesartan.

The other ingredients in the tablet core are:

- Lactose monohydrate
- Pregelatinised maize starch
- Copovidone
- Croscarmellose (E468)
- Anhydrous colloidal silica (E551)
- Magnesium stearate (E470b)

The other ingredients in the film coating are:

- Hypromellose (E464)
- Macrogol 400
- Titanium dioxide (E171)

### **What Irbesartan Clonmel 75 mg, 150 mg and 300 mg film-coated tablets look like and contents of the pack**

Irbesartan Clonmel 75 mg film-coated tablets are white, biconvex, oval-shaped and approximately 10 mm long.

Irbesartan Clonmel 150 mg film-coated tablets are white, biconvex, oval-shaped and approximately 13 mm long.

Irbesartan Clonmel 300 mg film-coated tablets are white, biconvex, oval-shaped and approximately 16 mm long.

Irbesartan Clonmel 75 mg film-coated tablets

Pack sizes of 10, 14, 28, 30, 50, 56, 60, 90 or 98 tablets in PVC/PVDC/Aluminium blisters.

Pack sizes of 10 x 1, 14 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1, 60 x 1, 90 x 1 or 98 x 1 tablets in PVC/PVDC/Aluminium perforated unit dose blisters.

Irbesartan Clonmel 150 mg film-coated tablets

Pack sizes of 10, 14, 28, 30, 50, 56, 90, 98 or 100 tablets in PVC/PVDC/Aluminium blisters.

Pack sizes of 10 x 1, 14 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1, 90 x 1, 98 x 1 or 100 x 1 film-coated tablets in PVC/PVDC/Aluminium perforated unit dose blisters.

Irbesartan Clonmel 300 mg film-coated tablets

Pack sizes of 10, 14, 28, 30, 50, 56, 90, 98, 100, 126 or 154 tablets in PVC/PVDC/Aluminium blisters.

Pack sizes of 10 x 1, 14 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1, 90 x 1, 98 x 1, 100 x 1, 126 x 1 or 154 x 1 film-coated tablets in PVC/PVDC/Aluminium perforated unit dose blisters.

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, 61118 Bad Vilbel, Germany

Centrafarm Services B.V., Nieuwe Donk 9, 4879 AC Etten Leur, The Netherlands

S.A. Eurogenerics N.V., Heizel Esplanade Heysel B22, B-1020 Brussels, Belgium

PharmaCoDane ApS, Marielundvej 46A, DK-2730 Herlev, Denmark  
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

BE: Irbesartan EG 75 mg, 150 mg, 300 mg filmomhulde tabletten  
DE: Irbesartan STADA 75 mg, 150 mg, 300 mg Filmtabletten  
DK: Irbesartan STADA 150 mg, 300 mg filmovertrukne tabletter  
FR: IRBESARTAN EG 75 mg, 150 mg, 300 mg comprimés pelliculés  
IE: Irbesartan Clonmel 75 mg, 150 mg, 300 mg film-coated tablets  
LU: Irbesartan EG 75 mg, 150 mg, 300 mg comprimés pelliculés  
NL: Irbesartan CF 75 mg, 150 mg, 300 mg filmomhulde tabletten  
PT: Irbesartan Stada 75 mg, 150 mg, 300 mg  
RO: Irbesartan HF 150 mg, 300 mg comprimate filmate  
SE: Irbesartan STADA 75 mg, 150 mg, 300 mg filmdragerade tabletter

**This leaflet was last revised in July 2016.**