

## Package leaflet: Information for the user

### **Irbesartan Accord 75mg Film-coated Tablets** **Irbesartan Accord 150mg Film-coated Tablets** **Irbesartan Accord 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 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 Irbesartan Accord is and what it is used for
2. What you need to know before you take Irbesartan Accord
3. How to take Irbesartan Accord
4. Possible side effects
5. How to store Irbesartan Accord
6. Contents of the pack and other information

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

Irbesartan Accord 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 Accord prevents the binding of angiotensin -II to these receptors, causing the blood vessels to relax and the blood pressure to lower. Irbesartan Accord slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Irbesartan Accord is used in adult patients

- to treat high blood pressure (essential hypertension)
- to 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 Accord**

##### **Do not take Irbesartan Accord:**

- If you are allergic to irbesartan 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 Irbesartan Accord 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”

Irbesartan Accord should not be given to children and adolescents under 18 years of age.

##### **Warnings and Precautions:**

**Talk to your doctor or pharmacist before taking Irbesartan Accord and 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 receive Irbesartan Accord for diabetic kidney disease. In this case your doctor may perform regular blood tests, especially for measuring blood potassium levels in case of poor kidney function.
- if you develop low blood sugar levels (symptoms may include sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heart beat), particularly if you are being treated for diabetes.
- if you are going to have an operation (surgery) or be given anaesthetics

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

#### **Children and adolescents**

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

#### **Other medicines and Irbesartan Accord:**

Tell your doctor or pharmacist if you are taking, or 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 Tablets” 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
- reaglinide (medication used for lowering blood sugar levels)

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

#### **Irbesartan Accord with food and drink**

Irbesartan Accord 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 Irbesartan Accord before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Irbesartan Accord. Irbesartan Accord 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 Accord 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:**

Irbesartan Accord 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 Accord contains lactose (as lactose monohydrate)**

Irbesartan Accord contains lactose (as lactose monohydrate). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

#### **Irbesartan Tablets contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

<b>3. How to take Irbesartan Accord</b>
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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 Tablets is for oral use. The tablets should be swallowed with a sufficient amount of fluid (e.g. one glass of water). You can take Irbesartan Tablets with or without food. You should try to take your daily dose at about the same time each day. It is important that you continue to take Irbesartan Tablets until your doctor tells you otherwise.

- **Patients with high blood pressure**

The usual dose is 150 mg once a day. The dose may later be increased to 300 mg once daily depending on blood pressure response.

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

In patients with high blood pressure and type 2 diabetes, 300 mg once daily is the preferred 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 effects should be reached 4-6 weeks after beginning treatment.

### **Use in Children and adolescents**

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

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

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

### **If you forget to take Irbesartan Accord**

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 this medicine and **contact your doctor immediately**.

The frequency of the side effects listed below is defined using the following convention:

Very common: may affect more than 1 in 10 people  
Common: may affect up to 1 in 10 people

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

Side effects reported in clinical studies for patients treated with Irbesartan Accord were:

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 test may show an increase in levels of potassium.

Common (may affect up to 1 in 10 people)

- Dizziness
- Feeling sick/vomiting and fatigue

- Blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatinase 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

Some undesirable effects have been reported since marketing of Irbesartan Accord. Undesirable effects where the frequency is not known are:

- Reduced number of platelets
- feeling of spinning
- Headache
- Taste disturbance
- Ringing in the ears
- Muscle cramps
- Pain in joints and muscles
- Abnormal liver function
- Increased blood potassium levels
- Impaired renal function
- Inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis).
- Decreased number of red blood cells (anaemia – symptoms may include tiredness, headaches, being short of breath when exercising, dizziness and looking pale)
- Severe allergic reactions (anaphylactic shock) and low blood sugar levels

Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.

If you get any side effects talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist. 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 Irbesartan Accord**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after 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.
- No special storage conditions recommended.
- Do not remove the tablets from the blister pack until you are ready to take the medicine.
- 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 Irbesartan Accord contains:**

The active substance is Irbesartan . Each film-coated tablet of Irbesartan Accord 75 mg, 150 mg, 300 mg contains 75 mg, 150 mg, 300 mg of Irbesartan.

The other ingredients in the tablet core are Lactose monohydrate, Croscarmellose Sodium (E468), Cellulose microcrystalline (E460), Hypromellose E5 (E464), Silica, colloidal anhydrous (E551), Magnesium stearate (E572).

The other ingredients in the tablet coating are hypromellose E5 (E464), macrogol 400, lactose monohydrate and titanium dioxide (E 171)

**What Irbesartan Accord 75,150, 300 mg Tablets looks like and content of the pack:**

Irbesartan Accord 75 mg Tablets are White to off white, oval, biconvex, film coated tablet debossed 'I 75' on one side and plain on other side.

Irbesartan Accord 150 mg Tablets are White to off white, oval, biconvex, film coated tablet debossed 'I 150' on one side and plain on other side.

Irbesartan Accord 300 mg Tablets are White to off white, oval, biconvex, film coated tablet debossed 'I 300' on one side and plain on other side.

Irbesartan Accord, 75 mg, 150 mg and 300 mg Tablets are supplied in blister packs of 8, 14, 28, 30, 56, 64, 90 and 98 Tablets.

**Not all pack sizes are marketed.**

**Marketing authorization holder**

Accord Healthcare Ireland Limited  
Euro House,  
Euro Business Park,  
Little Island,  
Cork T45 K857,  
Ireland

**Manufacturer:**

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

Accord Healthcare B.V.,  
Winthontlaan 200,  
3526 KV Utrecht,  
The Netherlands

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

Country name	Proposed name
The Netherland	Irbesartan Accord 75/150/300 mg filmmomhulde tabletten
Slovenia	Irbesartan Accord 75/150/300 mg filmsko obložene tablete
Slovakia	Irbesartan Accord 150 mg filmom obalene tablety
Bulgaria	Irbesartan Accord 150/300 mg film-coated Tablets
Latvia	Irbesartan Accord 150/300 mg apvalkotās tabletes
Luthuania	Irbesartan Accord 75/150/300 mg plėvele dengtos tabletės
Cyprus	Irbesartan Accord 150mg επικαλυμμένα με λεπτό υμένιοx δισκία
Denmark	Irbesartan Accord 150/300 mg Film-coated Tablets
France	Irbesartan Accord 75/150/300 mg comprimé pelliculé
Ireland	Irbesartan Accord 75/150/300 mg Film-coated Tablets
Italy	Irbesartan Accord
Norway	Irbesartan Accord
Sweden	Irbesartan Accord 75/150/300 mg filmdragerade tabletter
United kingdom	Irbesartan Accord 75/150/300 mg Film-coated Tablets

(Northern Ireland)	
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**The leaflet was last revised in.**