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Package leaflet: Information for the user

Irbesartan 75 mg Film-coated Tablets Irbesartan 150 mg Film-coated Tablets Irbesartan 300 mg 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 Tablets are and what they are used for
2. What you need to know before you take Irbesartan Tablets
3. How to take Irbesartan Tablets
4. Possible side effects
5. How to store Irbesartan Tablets
6. Contents of the pack and other information

1. What Irbesartan Tablets are and what they are used for

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

Irbesartan Tablets 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 Tablets

Do not take Irbesartan Tablets:
- 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 Tablets 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 Tablets 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 Tablets 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**
- 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.

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

See also information under the heading “Do not take Irbesartan Tablets”.

You must tell your doctor if you think you are (or might become) pregnant. Irbesartan Tablets 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 have not yet been fully established.

Other medicines and Irbesartan Tablets:
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 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
- repaglinide (medication used for lowering blood sugar levels).

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

Irbesartan Tablets with food and drink
Irbesartan Tablets 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 Tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Irbesartan Tablets. Irbesartan 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. Irbesartan 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.

Driving and using machines:
Irbesartan Tablets 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 Tablets contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

3. How to take Irbesartan Tablets

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.** Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take Irbesartan Tablets 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 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.

Your 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 Tablets 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 Tablets than you should
If you accidentally take too many tablets, contact your doctor immediately.

If you forget to take Irbesartan Tablets
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
Rare: may affect up to 1 in 1,000 people

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Side effects reported in clinical studies for patients treated with Irbesartan Tablets 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 tests may show an increased level 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 (creatine 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.

Rare (may affect up to 1 in 1,000 people):
• Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.

Some undesirable effects have been reported since marketing of Irbesartan Tablets.
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.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Irbesartan Tablets

• 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.
• 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 Tablets contain:
The active substance is irbesartan. Each film–coated tablet of Irbesartan 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 Tablets look like and contents of the pack:

Irbesartan 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 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 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, 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
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