

Package leaflet: Information for the user

Irbesartan 75mg film-coated tablets Irbesartan 150mg film-coated tablets Irbesartan 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.

These tablets are available in multiple strengths but will be referred to as Irbesartan Tablets throughout this leaflet.

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
3. How to take Irbesartan
4. Possible side effects
5. How to store Irbesartan
6. Contents of the pack and other information

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

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

Irbesartan 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

Do not take Irbesartan

- if you are **allergic** (hypersensitive) 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 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 alicikiren.

Warnings and precautions

Talk to your doctor or pharmacist before taking irbesartan 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 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 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.
 - Alicikiren

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".

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



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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

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 alicikiren (see also information under the headings "Do not take Irbesartan" 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 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 before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Irbesartan. Irbesartan 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 are not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breastfeed, 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

No studies on the effects on the ability to drive and use machines have been performed. Irbesartan tablets are 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 monohydrate. If you have been told by your doctor that you have intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine.

3. How to take Irbesartan tablets

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

Method of administration

Irbesartan tablets are 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.

The recommended dose is

- **Patients with high blood pressure**
The usual dose is 150mg once a day. The dose may later be increased to 300mg 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, 300mg 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 effect 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 Irbesartan 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 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, fatigue and blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatin 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. Undesirable effects where the frequency is not known are: feeling of spinning, headache, taste disturbance, ringing in the ears, muscle cramps, pain in joints and muscles, abnormal liver function, increased blood potassium levels, reduced number of platelets, impaired kidney function, and inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis and severe allergic reactions (anaphylactic shock). 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Irbesartan

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

This medicinal product does not require any special

storage conditions.

Do not use this medicine if you notice (description of the visible signs of deterioration).

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 tablet contains 75mg, 150mg & 300mg of Irbesartan.
- The other ingredients are: Tablet Core: Lactose Monohydrate, Sodium starch glycolate, Polysorbate 80, Hydroxypropylmethyl cellulose 5 cps, Microcrystalline cellulose, Colloidal silicon dioxide, magnesium stearate.

Coating: Hydroxypropylmethyl cellulose 5 cps, Polyethylene glycol 6000

What Irbesartan Tablets looks like and contents of the pack

The 75mg tablets are white to off-white, oval, biconvex, film-coated tablets, engraved with '75' on one face and plain on the other face.

The 150mg tablets are white to off-white, oval, biconvex, film-coated tablets, engraved with '150' on one face and plain on the other face.

The 300mg tablets are white to off-white, oval, biconvex, film-coated tablets, engraved with '300' on one face and plain on the other face.

Pack contents are 7, 10, 14, 28, 56 and 98 tablets in PVC/ACLAR/Aluminium blisters or Aluminium-Aluminium blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder & Manufacturer

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

UK: Irbesartan 75mg/150mg/300mg film-coated tablets
DE: Irbesartan-Micro labs 75mg/150mg/300mg Filmtabletten

This leaflet was last approved on December 2019



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