



PATIENT INFORMATION LEAFLET

PATIENT SUMMARY OF INFORMATION ABOUT IRBIS 150 (Irbesartan Tablets 150 mg)

Read all of this leaflet carefully before you start having 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 is and what it is 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 is and what it is used for

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 also 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** 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 aliskiren.

Warnings and precautions

Talk to your doctor or pharmacist before taking Irbesartan:

- if you have had, or during treatment have, excessive **vomiting** (being sick) **or diarrhea**
- if you have been taking **‘water tablets’** or have been on a **low sodium diet**
- if you suffer from **kidney problems, including narrowing of the kidney artery or have had a kidney transplant**
- if you suffer from **heart problems, including a narrowing of the valves in the heart, an enlarged heart muscle** or a **weakness of the heart muscle** (heart failure)
- **if you have a narrowing of the heart blood vessels**, which may cause chest pain e.g. angina
- 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 suffer from **primary aldosteronism** (a condition related to high production of the hormone aldosterone, which causes sodium retention and, in turn, an increase in blood pressure)
- if you are of **Afro-Caribbean origin**, as irbesartan may not be as effective at lowering your blood pressure
 - 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”.

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 to your baby if used at that stage (see pregnancy section).

During treatment

You should also tell your doctor:

- if you are going to have an operation (surgery) or be given anaesthetics

Children and adolescent

This medicine 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 aliskiren (see also information under the heading “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 (water tablets) or medicines that may increase the levels of potassium in the blood e.g. heparin
- medicines containing lithium (used to treat mental health problems)

If you take certain painkillers, called non-steroidal anti-inflammatory drugs, or “COX-2” inhibitors e.g. celecoxib or acetylsalicylic acid, the effect of irbesartan may be reduced.

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 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 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 contains lactose and sodium

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.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodiumfree'.

3. How to take Irbesartan

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 is for oral use. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take Irbesartan 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 until your doctor tells you otherwise.

- Patients with high blood pressure

The recommended 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 recommended maintenance dose for the treatment of associated kidney disease.

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The doctor may advise a lower dose, especially when starting treatment if you are on haemodialysis or are aged 75 or older.

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

Use in children and adolescents

Irbesartan 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 than you should

If you accidentally take too many tablets, contact your doctor immediately. You may feel dizzy and/or feel your heart beating faster or slower.

If you forget to take Irbesartan

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. **If you notice any of the following side effects, stop taking this medicine and contact your doctor or go to the nearest hospital casualty department straight away:**

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

- Serious allergic reaction with symptoms such as itchy red rash, feeling dizzy or faint, swelling of the face, lips and/or tongue which may cause difficulty breathing.
- Yellowing of the skin and whites of the eyes, severe upper stomach pain and feeling and being sick, which may be due to liver problems.
- Rash with raised purple spots and flat red areas caused by inflammation of small blood vessels (vasculitis).
- Passing water more often, in greater amounts which is pale in colour, or straining or being unable to pass water or less often, which may be darker in colour or may even be bloody. This may be due to a problem with the kidneys.

Other possible side effects

Very common (may affect up to 1 in 10 people):

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

Common:

- dizziness
- feeling sick/being sick (vomiting)
- feeling tired (fatigue)
- blood tests may show raised levels of an enzyme that measures how the muscles and heart are working (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
 - blood tests may show decreased levels of a protein in the red blood cells (haemoglobin) were also reported.

Uncommon:

- you feel your heart beating faster (heart rate increased)
- flushing
- cough
- diarrhoea
- indigestion/heartburn
- sexual dysfunction (problems with sexual performance)
- chest pain

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

- bleeding or bruising more easily which may be caused by a reduced number of platelets (cells in the blood which help it to clot)
- feeling of spinning
- headache
- taste disturbance
- ringing in the ears

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- muscle cramps
- pain in joints and muscles
- blood tests may show that the liver is not working properly
- blood tests may show increased blood potassium levels

Reporting of side effects

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

5. How to store Irbesartan

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, label or blister.

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

The in-use shelf-life of the product when stored in plastic bottles is 90 days once opened.

This medicine does not require any special 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 protect the environment.

6. What Irbesartan looks like and contents of the pack

Each Film coated tablet contains 150 mg of Irbesartan USP.

White to off white coloured, capsule shaped, biconvex, film coated tablets debossed with '159' on one side and 'H' on the other side.

3 x 10's Blister pack

Marketing Authorization Holder

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