

Package leaflet: Information for the patient

Irbesartan 75 mg tablets

Irbesartan 150 mg tablets

Irbesartan 300 mg tablets

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 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 diarrhoea**
- 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 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 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)
- repaglinide (medication used for lowering blood sugar levels)

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 'sodium-free'.

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.

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):

- 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 (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
 - 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)
- tiredness, headaches, being short of breath when exercising or dizziness and looking pale which may be caused by a reduced number of red blood cells (anaemia)
- feeling of spinning

- headache
- taste disturbance
- ringing in the ears
- 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
- low blood sugar 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.

You can also report side effects directly via the 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

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. Contents of the pack and other information

What Irbesartan contains

The active substance is irbesartan.

Each 75 mg tablet contains 75 mg of irbesartan.

Each 150 mg tablet contains 150 mg of irbesartan.

Each 300 mg tablet contains 300 mg of irbesartan.

The other ingredients are lactose monohydrate (see section 2 of this leaflet 'Irbesartan contains lactose'), povidone, microcrystalline cellulose, croscarmellose sodium, magnesium stearate and silica and colloidal anhydrous.

What Irbesartan looks like and contents of the pack

75 mg tablets: Round, white to off-white tablets, with sides that curve outwards, marked with "M" on one side, "IN1" on other side

150 mg tablets: Round, white to off-white tablets, with sides that curve outwards, marked with "M" on one side, "IN2" on other side

300 mg tablets: Oval, white to off white tablets, with sides that curve outwards, marked with "M" on one side, "IN3" on other side

Irbesartan is available in blister packs of 10, 14, 28, 30, 56, 57, 58, 60, 84, 90, 98 and 100, calendar packs of 14, 28, 56, 84 and 98 tablets and plastic bottles of 30 (for 150 mg and 300 mg only), 500 and 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturers:

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Mylan Hungary Kft, H-2900 Komarom, Mylan utca 1, Hungary

Generics [UK] Limited, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

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