

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, pharmacist or nurse.
- 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, pharmacist or nurse. 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 do 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 further 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 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 DO YOU NEED TO KNOW
BEFORE YOU TAKE IRBESARTAN**

Do not take Irbesartan:

- If you are allergic to irbesartan or any 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 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 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.

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).

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.

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.

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.

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” and “warnings and precautions”).

Irbesartan with food, drink and alcohol

Irbesartan can be taken with or without food.

**Pregnancy, breast-feeding and fertility
Pregnancy**

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. 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 monohydrate

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 medicinal products.

Information on sodium content

This medicine contains less than 1mmol 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.

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 (two tablets a day) 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 (two tablets a day) 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.

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 your medicine 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 your medicine until your doctor tells you otherwise.

For 150mg and 300mg tablets, the score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

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.

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 product, ask your doctor, pharmacist or nurse.

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.**

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 (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 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, jaundice (yellowing of the skin and/or whites of the eyes).
- **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
- **Not known (frequency cannot be estimated from the available data):**
vertigo, reduced number of platelets, headache, taste disturbance, ringing in the ears, muscle cramps and pain in joints and muscles, abnormal liver function, increased blood potassium levels, 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) decreased number of red blood cells (anaemia - symptoms may include tiredness, headaches, being short of breath when exercising, dizziness and looking pale), low blood sugar levels.

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 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 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.
- This medicinal product does not require any special storage conditions.
- Do not throw away any medicine 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 FURTHER INFORMATION

What Irbesartan contains

- Each tablet contains 75mg or 150mg or 300mg irbesartan which is the active substance.
- The other ingredients are: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, poloxamer 188, pregelatinised maize starch and magnesium stearate.
The tablet coating contains hydroxypropyl cellulose, hypromellose, titanium dioxide and talc.

What Irbesartan looks like and contents of the pack

- 75mg: white to off-white, oblong, biconvex, film-coated tablets, debossed with 'BL' on one side and '75' on the other.
- 150mg: white to off-white, oblong, biconvex, film-coated tablets debossed with 'B' and 'L' on either side of the score line and '150' on the other.
- 300mg: white to off-white, oblong, biconvex, film-coated tablets debossed with 'B' and 'L' on either side of the score line and '300' on the other.
- Irbesartan is supplied in blister packs of 14, 28, 30, 56, 84, 90 or 98 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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PL 17907/0421

Irbesartan 150mg film-coated tablets;

PL 17907/0422

Irbesartan 300mg film-coated tablets;

PL 17907/0423

This leaflet was last revised in January 2025

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