

Package leaflet: Information for the user

Irbesan 75 mg Film-coated tablets
Irbesan 150 mg Film-coated tablets
Irbesan 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 Irbesan is and what it is used for
2. What you need to know before you take Irbesan
3. How to take Irbesan
4. Possible side effects
5. How to store Irbesan
6. Contents of the pack and other information

1. What Irbesan is and what it is used for

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

Irbesan tablets are 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 Irbesan

Do NOT take Irbesan:

- if you are **allergic** to irbesartan or any of the ingredients of this medicine (listed in section 6)
- if you are **more than 3 months pregnant**. (It is also better to avoid Irbesan 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 before taking Irbesan 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 Irbesan 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.
 - **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 use Irbesan”.

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

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 Irbesan” 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.

Irbesan with food and drink

Irbesan 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 Irbesan before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Irbesan. Irbesan 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. Irbesan 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

No studies on the effects on the ability to drive and use machines have been performed. Irbesan 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.

Irbesan contains lactose.

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.

3. How to take Irbesan

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

Irbesan is for **oral use**. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take Irbesan 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 Irbesan 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.

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

Irbesan should not be given to children and adolescents under 18 years of age. If a child swallows some tablets, contact your doctor immediately.

If you take more Irbesan than you should

If you accidentally take too many tablets, contact your doctor immediately.

If you forget to take Irbesan

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 localized 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 Irbesan 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.

Some undesirable effects have been reported since marketing of irbesartan. 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 kidney function, and inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis). 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Irbesan

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 outer carton, the blister and bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

After first opening the bottles: 3 months.

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 Irbesan contains

- The active substance is Irbesartan. Each tablet contains 75, 150 or 300 mg irbesartan.
- The other ingredients are:
Tablet core:
Microcrystalline cellulose
Lactose monohydrate
Croscarmellose sodium
Silica, colloidal anhydrous
Hypromellose
Magnesium stearate.

Tablet coating:

Hypromellose
Hydroxypropylcellulose
Macrogol 6000
Lactose monohydrate
Titanium dioxide (E171)
Talc.

What Irbesan looks like and contents of the pack

Irbesan 75 mg Film-coated tablets are white, oval biconvex film-coated tablets, debossed with '75' on one side and scored on the other side.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Irbesan 150 mg Film-coated tablets are white, oval biconvex film-coated tablets, debossed with '150' on one side and scored on the other side.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Irbesan 300 mg Film-coated tablets are white, oval biconvex film-coated tablets, debossed with '300' on one side and scored on the other side.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Irbesan is available in blister (oPA/Al/PVC//Al or PVC/PVDC//Al) or in bottle (high density polyethylene (HDPE) container).

oPA/Al/PVC//Al or PVC/PVDC//Al blisters: 7, 10, 14, 20, 28, 30, 56, 60, 84, 90, 98, 100 film-coated tablets.

oPA/Al/PVC//Al or PVC/PVDC//Al unit dose blisters: 56x1, 100x1 film-coated tablets.

HDPE bottle: 100, 250 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Lek S.A., ul. Domaniewska 50 C, 02-672 Warsaw, Poland.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Salutas Pharma GmbH, Dieselstrasse 5, D-70839 Gerlingen, Germany.

Lek Pharmaceuticals d.d., Trimlini 2D 9220 Lendava, Slovenia.

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

Austria: Irbesartan Rowex 75 mg Filmtabletten
Irbesartan Rowex 150 mg Filmtabletten
Irbesartan Rowex 300 mg Filmtabletten
Ireland: Irbesan 75 mg Film-coated tablets
Irbesan 150 mg Film-coated tablets
Irbesan 300 mg Film-coated tablets

This leaflet was last revised in 08/2016.