

Package leaflet: Information for the patient
Irbesartan Rowa 75 mg tablets
Irbesartan Rowa 150 mg tablets
Irbesartan Rowa 300 mg 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. 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 Rowa is and what it is used for
2. What you need to know before you take Irbesartan Rowa
3. How to take Irbesartan Rowa
4. Possible side effects
5. How to store Irbesartan Rowa
6. Content of the pack and other information.

1. What Irbesartan Rowa is and what is used for

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

Irbesartan Rowa is used in adult patients

- to treat high blood pressure, (*essential hypertension*)
- to protect the kidney in patients with high blood pressure, type 2 diabetics and laboratory evidence of impaired renal function.

2. What you need to know before you take Irbesartan Rowa

Do not take Irbesartan Rowa

- if you are **allergic** (hypersensitive) 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 Rowa 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 Rowa tablets 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 Rowa 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.

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Irbesartan Rowa. Your doctor will decide on further treatment. Do not stop taking Irbesartan Rowa on your own.

See also information under the heading “Do not take Irbesartan Rowa”.

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

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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 Rowa” 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
- 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.

Irbesartan Rowa with food and drink

Irbesartan Rowa 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 Rowa before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Irbesartan Rowa. Irbesartan Rowa 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 Rowa 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 Rowa 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 Rowa tablets contain 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 product.

Irbesartan Rowa tablets contains sodium.

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

3. How to take Irbesartan Rowa

Always take Irbesartan Rowa tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Method of administration

Irbesartan Rowa 75 mg/150 mg/300 mg tablets are for oral use. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take Irbesartan Rowa 75 mg/150 mg/300 mg 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 Rowa 75 mg/150 mg/300 mg tablets 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

Irbesartan Rowa 75 mg/150 mg/300 mg 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 Rowa than you should

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

If you forget to take Irbesartan Rowa 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, irbesartan can cause side effects, although not everybody gets them. Some 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 this medicine 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

Rare: may affect up to 1 in 1.000 people.

Side effects reported in clinical studies for patients treated with this irbesartan were:

- Very common (may affect more than 1 user 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 1 to 10 people): dizziness, feeling sick/vomiting, fatigue and blood tests may show raised levels of an enzyme that measure 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, pain in joints or muscles and decreased levels of a protein in the red blood cells (haemoglobin) were also reported.
- Uncommon (may affect to 1 in 100 people): heart rate increased, flushing, cough, diarrhoea, indigestion/heartburn, sexual dysfunction (problems with the sexual performance), chest pain.

- 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.

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, decreased number of red blood cells (anaemia – symptoms may include tiredness, headaches, being short of breath when exercising, dizziness and looking pale), reduced number of platelets, abnormal liver function, increased blood potassium levels, impaired kidney function, and inflammation of small blood vessels mainly affecting the skin (condition known as leukocytoclastic vasculitis) and severe allergic reactions (anaphylactic shock) and low blood sugar levels. 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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Irbesartan Rowa

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.

Store in the original package in order to protect from light.

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 to protect the environment.

6. Contents of the pack and other information

What Irbesartan Rowa 75 mg/150 mg/300 mg tablets contain

- The active substance is irbesartan. Each tablet of Irbesartan Rowa 75 mg/ 150 mg/ 300 mg contains 75 mg/150 mg/300 mg of irbesartan respectively.
- The other ingredients are cellulose microcrystalline (E 460 (i)), croscarmellose sodium (E 468), lactose monohydrate, magnesium stearate (E 470b), silica colloidal anhydrous (E 551), maize starch, povidone K29/32 (E-1201) and hydrogenated castor oil.

What Irbesartan Rowa 75 mg/150 mg/300 mg tablets look like and contents of the pack

Irbesartan Rowa 75 mg tablets are white, cylindrical, biconvex tablets.

Irbesartan Rowa 150 mg tablets are white, cylindrical, biconvex, scored on one side tablets.

Irbesartan Rowa 300 mg tablets are white, oblong, biconvex, scored on one side tablets.

Irbesartan Rowa 75 mg/150 mg/300 mg tablets are supplied in blisters of pack sizes of 14, 28, 56 or 98.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Rowa Pharmaceuticals Ltd.
Newtown
Bantry
Co Cork
P75V009
Ireland

Manufacturer:

Laboratorios LICONSA, S.A.
Avda. Miralcampo, N° 7, Polígono Industrial Miralcampo
19200 Azuqueca de Henares (Guadalajara), SPAIN

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

75 mg:

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| Ireland: | Irbesartan Rowa 75 mg tablets |
| Netherlands: | Irbesartan Xiromed 75 mg |
| Austria: | Licolin 75 mg Tablette |

150 mg:

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| Ireland: | Irbesartan Rowa 150 mg tablets |
| Netherlands: | Irbesartan Xiromed 150 mg |
| Austria: | Licolin 150 mg Tablette |

300 mg:

| | |
|--------------|--------------------------------|
| Ireland: | Irbesartan Rowa 300 mg tablets |
| Netherlands: | Irbesartan Xiromed 300 mg |
| Austria: | Licolin 300 mg Tablette |

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