Package leaflet: Information for the user

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

1. What Irprestan is and what it is used for

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

Irprestan is used in adult patients
- to treat high blood pressure (*essential hypertension*)
- to protect the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function.

2. What you need to know before you take Irprestan

Do not take Irprestan
- 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 Irprestan 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 Irprestan
- if you suffer from **excessive vomiting or diarrhoea**
- if you suffer from **kidney problems**
- if you suffer from **heart problems**

- if you receive Irprestan 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 Irprestan"

You must tell your doctor if you think that you are (or might become) pregnant. Irprestan 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 (under 18 years) because the safety and efficacy have not yet been fully established.

Other medicines and Irprestan

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 take other precautions:
- if you are taking an ACE-inhibitor or aliskiren (see also information under the headings 'Do not take Irprestan' 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.

Irprestan with food and drink
Irprestan can be taken with or without food. The tablets should be swallowed with a drink of water.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Irprestan before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Irprestan. Irprestan 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. Irprestan 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
Irprestan 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 such activities.

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

3. How to take Irprestan

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The following strengths are available: 75 mg, 150 mg and 300 mg

Method of administration
Irprestan is for oral use and is taken with or without food. The tablets should be swallowed with a drink of water. You should try to take your daily dose at about the same time each day. It is important that you continue to take Irprestan 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 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
Irprestan 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 Irprestan than you should
If you accidentally take too many tablets, contact your doctor immediately. Symptoms of overdose can be hypotension and tachycardia; bradycardia.

If you forget to take Irprestan
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 Irprestan and contact your doctor immediately.

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

Very common side effects (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 side effects (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 (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 and decreased levels of a protein in the red blood cells (haemoglobin) were also reported.

Uncommon side effects (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: feeling of spinning, headache, taste disturbance, ringing in the ears, muscle cramps, pain in joints and muscles, abnormal liver function, increased blood potassium levels, reduced number of platelets, impaired kidney function, inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis) and severe allergic reactions (anaphylactic shock). Uncommon cases of yellowing of the skin and/or whites of the eyes (jaundice) 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, 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 Irprestan

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 or tablet container 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 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 Irprestan contains

- The active substance is irbesartan. Each tablet contains 75 mg, 150 mg or 300 mg of irbesartan.
- The other ingredients are: *tablet core:* croscarmellose sodium (E468), microcrystalline cellulose (E460), hypromellose (E464), mannitol (E421), magnesium stearate (E572), silica, colloidal anhydrous (E551); *tablet coating:* hydroxypropyl cellulose (E463), hypromellose (E464), macrogol 6000, titanium dioxide (E171).

What Irprestan looks like and contents of the pack

The 75mg tablets are white, elliptical, biconvex, film-coated tablets, marked 'I' on one side and '75' on the other side.

The 150mg tablets are white, elliptical, biconvex, film-coated tablets, marked 'I' on one side and '150' on the other side.

The 300mg tablets are white, elliptical, biconvex, film-coated tablets, marked 'I' on one side and '300' on the other side.

Pack sizes:

Blisters:
Irprestan 75 mg film-coated tablets: 14, 28, 30, 56, 84, 90, 98 tablets
Irprestan 150 mg film-coated tablets: 14, 28, 30, 56, 84, 90, 98 tablets
Irprestan 300 mg film-coated tablets: 14, 28, 30, 56, 84, 90, 98 tablets

Tablet containers:
Irprestan 75 mg film-coated tablets: 30, 60, 250 tablets
Irprestan 150 mg film-coated tablets: 30, 60, 250 tablets
Irprestan 300 mg film-coated tablets: 30, 60, 250 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Actavis Group PTC ehf
Reykjavikurvegur 76-78
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Iceland

Manufacturer
Balkanpharma Dupnitsa AD, 3 Samokovsko Shosse Str., Dupnitsa 2600, Bulgaria.

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