Package leaflet: Information for the user

Irbesartan Actavis 75 mg film-coated tablets
/…/ 150 mg film-coated tablets
/…/ 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 /…/ is and what it is used for

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

/.../ 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 /…/

Do not take /.../
- 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/…/ 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 /…/
- if you suffer from **excessive vomiting or diarrhoea**
- if you suffer from **kidney problems**
- if you suffer from **heart problems**
- if you receive /.../ 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 a 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 /…/"

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

You must tell your doctor if you think that you are (or might become) pregnant. /…/ 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 /…/
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 /…/" 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.

/.../ with food and drink
/.../ 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 /…/ before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of /…/. /…/ 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. /…/ 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
/.../ 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.

/.../ 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 /…/

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
/.../ 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 /.../ 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
/.../ 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 /.../ 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 /.../
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 /…/ 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 (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 (may affect up to 1 in 100 people): heart rate increased, flushing, cough, diarrhoea, indigestion/heartburn, sexual dysfunction (problems with sexual performance), chest pain.

Rare side effects (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 (frequency cannot be estimated from the available data) 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, 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, impaired kidney function, inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis), severe allergic reactions (anaphylactic shock) and low blood sugar levels. 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store /…/

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 /…/ 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 /…/ looks like and contents of the pack

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

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

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

Pack sizes:

Blisters:
/…/ 75 mg film-coated tablets: 10, 14, 28, 30, 56, 84, 90, 98, 100 tablets
/…/ 150 mg film-coated tablets: 10, 14, 28, 30, 56, 84, 90, 98, 100 tablets
/…/ 300 mg film-coated tablets: 10, 14, 28, 30, 56, 84, 90, 98, 100 tablets

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing authorisation holder
<[To be completed nationally]>

Manufacturer
<[To be completed nationally]>

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

<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

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