

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 Irbesartan Ranbaxy is and what it is
- What you need to know before you take Irbesartan Ranbaxy
- How to take Irbesartan Ranbaxy
- Possible side effects
- How to store Irbesartan Ranbaxy
- Contents of the pack and other information

1. What Irbesartan Ranbaxy is and what it is used for

Irbesartan belongs to a group of medicines known as angiotensin-II receptor blocker. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels causing narrowing of blood vessels. 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 adults for the treatment of high blood pressure (essential hypertension) and for the protection of the kidney in hypertensive patients, type 2 diabetic patients and laboratory evidence of impaired kidney function.

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

Do not take Irbesartan Ranbaxy

- if you are allergic to irbesartan or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, swelling of face, lips, or hands/feet, or breathing difficulties.
- 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.

If you think this applies to you, do not take the tablets, talk to your doctor and follow the advice given Ask your doctor if you are not sure whether you can take Irbesartan Ranbaxy.

Warnings and precautions

Talk to your doctor or pharmacist before taking Irbesartan Ranbaxy

- if you suffer from excessive vomiting or
- if you are on diuretic (water tablet) therapy or on restricted dietary salt intake.
- if you suffer from renovascular hypertension [hypertension due to narrowing of kidney blood vessels (renal artery stenosis)], use of irbesartan may cause severe decrease in your blood pressure
- and kidney insufficiency.

 if you suffer from **kidney disease**: In this case your doctor may perform regular blood tests, especially for measuring blood potassium levels and creatinine levels in case of poor kidney function.
- if you have an aortic, mitral valve stenosis (narrowing of heart valves) or obstructive hypertrophic cardiomyopathy (disease of the muscle of the heart in which a portion of the muscle
- if you are suffering from primary aldosteronism (a syndrome associated with increased secretion of a hormone called aldosterone by the adrenal gland characterised by high blood pressure, headache, and muscle weakness): Irbesartan Ranbaxy may not decrease blood pressure.
- if you are hypertensive and have diabetic kidnev disease, therapeutic effects of Irbesartan Ranbaxy may vary.
- if you are suffering from severe heart failure or kidney disease treatment with Irbesartan Ranbaxy may cause acute fall in blood pressure, increase in blood urea and creatinine, kidney failure and decrease in production of urine.
- If you are going to have an operation (surgery) or need an anaesthetic, tell the doctor about your
- 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.

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 Ranbaxy'

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

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Children and adolescents

Irbesartan Ranbaxy should not be given to children and adolescents (under 18 years) because safety and efficacy has not yet been fully established.

Other medicines and Irbesartan Ranbaxy

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important to inform your doctor if you are taking any of the following medicines:

- Diuretics (water tablets) and other antihypertensive (blood pressure lowering medicines) drugs: These drugs may increase the blood pressure lowering effects of irbesartan
- Potassium supplements and potassiumsparing diuretics: use at the same time may increase blood potassium levels.
- Lithium (medicine used to treat manicdepressive disorder): increase in blood lithium levels and toxicity may occur if lithium is administered at the same time as Irbesartan Ranbaxy.
- Non steroidal anti inflammatory drugs (medicines used to treat pain and fever): decrease in blood pressure lowering effect may occur; may lead to an increased risk of worsening of kidney function, including possible kidney failure, and an increase in blood potassium. Caution should be exercised if you are an older person.

Your doctor may need to change your dose and/or to take other precautions if you are taking an ACEinhibitor or aliskiren (see also information under the headings "Do not take Irbesartan Ranbaxy" and "Warnings and precautions")

Irbesartan Ranbaxy with food and drink

Irbesartan Ranbaxy can be taken with or without food.

Pregnancy, breast-feeding and fertility

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

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 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.

Breastfeeding

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.

Fertility

In animal studies Irbesartan had no effect on fertility

Driving and using machines

Irbesartan Ranbaxy is unlikely to affect your ability to drive and use machines. However, occasionally dizziness or weariness may occur during treatment of high blood pressure. If you experience these, you should consult your doctor before attempting such

Irbesartan Ranbaxy 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 medicinal product.

3. How to take Irbesartan Ranbaxy

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

Dosage

The recommended initial and maintenance dose is 150 mg once a day. Your doctor may increase your dose to 300 mg once daily depending on blood pressure response

In patients with high blood pressure and type 2 diabetes, 300 mg once daily is the preferred maintenance dose for the treatment of associated

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.

If you have liver disease your doctor would decide appropriate dosage for you.

The maximal blood pressure lowering effect should be reached 4 to 6 weeks after beginning treatment.

Irbesartan Ranbaxy is for oral use. The film-coated tablets should be swallowed with sufficient amount of water. To help you remember to take your medicine, try to get into the habit of taking it at the same time each

Use in children and adolescents

Irbesartan Ranbaxy film-coated tablets are not recommended in children and adolescents below 18

If you take more Irbesartan Ranbaxy than you should

If you accidentally take too many tablets, or someone else swallows some, contact your doctor or go to the nearest hospital casualty department immediately. Take this leaflet or some tablets with you so your doctor will know what you have taken.

The most likely manifestations expected to occur in case of an overdose are low blood pressure and increased rate of heart beat . Decreased heart beat rate could also occur.

If you forget to take Irbesartan Ranbaxy

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 stop taking Irbesartan Ranbaxy

Take your tablets as directed and for as long as directed. Do not stop taking them even if you feel better, as otherwise the symptoms may return. Do not stop taking your medicine suddenly unless told to do so by your doctor.

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.

Serious side effects

Cases of allergic skin reactions (rash, hives), as well as localised swelling of the face, lips and/or tongue have been reported in patients taking irbesartan (frequency not known). If you think you are developing such a reaction or get short of breath stop taking Irbesartan Ranbaxy and seek immediate medical attention.

Other side effects

The following side effects have been reported.

Common (may affect up to 1 in 10 people):

- feeling sick (nausea) / being sick (vomiting)

In patients with high blood pressure and type 2 diabetes with kidney disease, the following additional common side effects may occur:

- low blood pressure and dizziness (especially when getting up from a lying or sitting position)
- pain in bones and muscles

Uncommon side effects (may affect up to 1 in 100 people)

- fast heart beat (tachycardia)
- flushing cough
- diarrhoea
- indigestion/heart burn
- yellowing of the skin and/or whites of eyes, also called jaundice
- problems with sexual performance
- chest pain.

Not known side effects (frequency cannot be established from available data)

- headache
- taste disturbance
- · ringing in the ears, feeling of spinning
- muscle cramps
- pain in joints and muscles
- Inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis)
- yellowing of skin and whites of eyes with decreased appetite, abdominal pain (these may be manifestations of a liver problem)
- kidney problems including kidney failure

There may be changes in the results of certain laboratory tests

- decrease in haemoglobin (pigment in red blood
- increased blood potassium level
- abnormal liver function tests
- increase in plasma creatinine, creatine kinase

Therefore, your doctor may wish to do blood tests occasionally.

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, ÍRL-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 Irbesartan Ranbaxy

Keep this medicine out of the sight and reach of

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 to protect from light. This medicine does not require any special temperature 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.

${\bf 6.\,Contents\,of\,the\,pack\,and\,other\,information}$

What Irbesartan Ranbaxy contains

The active substance is irbesartan. Each film-coated tablet of Irbesartan Ranbaxy 75 mg contains 75 mg irbesartan. Each film-coated tablet of Irbesartan Ranbaxy 150

mg contains 150 mg irbesartan. Each film-coated tablet of Irbesartan Ranbaxy 300 mg contains 300 mg irbesartan.

The other ingredients are lactose monohydrate, cellulose microcrystalline, hypromellose, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate, opadry white (composition: hypromellose, macrogol 4000, titanium dioxide and lactose monohydrate).

What Irbesartan Ranbaxy looks like and contents of the pack

Irbesartan Ranbaxy 75mg film-coated tablets are white to off-white, film coated oval shaped, biconvex tablet debossed with 'I3'on one side and plain on the

Irbesartan Ranbaxy 150mg film-coated tablets are white to off-white, film coated oval shaped, biconvex tablet debossed with 'I4'on one side and plain on the

Irbesartan Ranbaxy 300mg film-coated tablets are white to off-white, film coated oval shaped, biconvex tablet debossed with 'I5'on one side and plain on the

Irbesartan Ranbaxy is supplied in clear transparent PVC/PE/PVdC/aluminium blister packs of 1, 14, 28, 30, 56, 60, 84, 90 or 98 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder Ranbaxy Ireland Ltd., Spafield, Cork Road, Cashel,

Manufacturer:

Ireland

Italy

Sweden

Co. Tipperary, Ireland

Ranbaxy Ireland Limited, Spafield, Cork Road, Cashel, Co-Tipperary, Republic of Ireland. S.C. Terapia S.A., 124 Fabricii Street, 400 632 Cluj Napoca, Romania.

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

Irbesartan Ranbaxy 75mg, 150mg France and 300mg comprimé pelliculé Greece Irbesartan 75mg, 150mg and 300mg Επικαλυμμένα με λεπτό υμένιο δισκία

Irbesartan Ranbaxy 75mg, 150mg and 300mg film-coated tablets Irbesartan Ranbaxy 75mg,

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and 300mg filmomhulde tabletten Irbesartan Terapia 150mg and 300mg comprimate filmate Irbesartan Ranbaxy 150mg and Spain 300mg comprimidos recubiertos

con pelicula EFG

Irbesartan Ranbaxy 150/300mg

filmdragerade tabletter This leaflet was last revised in September 2014

Black

Irbesartan PI size: 140 x 400 mm

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J29/Sep/2014-V02

Market: Ireland

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