

Package leaflet: Information for the patient

Irbesartan/Hydrochlorothiazide 150 mg/12.5 mg Film-coated Tablets Irbesartan/Hydrochlorothiazide 300 mg/12.5 mg Film-coated Tablets Irbesartan/Hydrochlorothiazide 300 mg/25 mg Film-coated Tablets Irbesartan and Hydrochlorothiazide

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/Hydrochlorothiazide tablets are and what are they used for
2. What you need to know before you take Irbesartan/ Hydrochlorothiazide tablets
3. How to take Irbesartan/ Hydrochlorothiazide tablets
4. Possible side effects
5. How to store Irbesartan/ Hydrochlorothiazide tablets
6. Contents of the pack and other information.

1. What Irbesartan/Hydrochlorothiazide tablets are and what are they used for

Irbesartan/Hydrochlorothiazide tablet is a combination of two active substances: irbesartan and hydrochlorothiazide.

Irbesartan belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body that binds to receptors in blood vessels causing them to tighten. 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.

Hydrochlorothiazide is one of a group of medicines (called thiazide diuretics) that causes increased urine output and so causes a lowering of blood pressure.

The two active ingredients in Irbesartan/Hydrochlorothiazide tablets work together to lower blood pressure further than if either was given alone.

Irbesartan/Hydrochlorothiazide Tablets are used to treat high blood pressure, when treatment with irbesartan or hydrochlorothiazide alone did not provide adequate control of your blood pressure.

2. What you need to know before you take Irbesartan/Hydrochlorothiazide tablets

Do not take Irbesartan/Hydrochlorothiazide tablets:

- If you are **allergic** to irbesartan or any of the other ingredients of this medicine listed in section 6
- If you are **allergic** to hydrochlorothiazide or any other sulfonamide-derived medicines.
- If you are **more than 3 months pregnant** (It is also better to avoid Irbesartan/Hydrochlorothiazide in early pregnancy – see pregnancy section)
- If you have **severe liver or kidney problems**
- If you have **difficulty in producing urine**
- If your doctor determines that you have **persistently high calcium or low potassium levels in your blood.**
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine called aliskiren.

Children and adolescents

Irbesartan/Hydrochlorothiazide tablets should not be given to children and adolescents (under 18 years).

Warnings and precautions

Talk to your doctor before taking Irbesartan/Hydrochlorothiazide tablets and if any of the following apply to you :

- If you get excessive **vomiting, or diarrhoea**
- If you suffer from **kidney problems** or have a **kidney transplant**
- If you suffer from **heart problems**
- If you suffer from **liver problems**
- If you suffer from **diabetes**
- If you suffer from **lupus erythematosus** (also known as lupus or SLE).
- If you suffer from **primary aldosteronism** (a condition related to high production of the hormone aldosterone, which causes sodium retention and, in turn, an increase in blood pressure)
- 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 Irbesartan/Hydrochlorothiazide tablets”.

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

You should also tell your doctor:

- if you are on a **low-salt diet**
- if you have signs such as **abnormal thirst, dry mouth, general weakness, drowsiness, muscle pain or cramps, nausea, vomiting**, or an **abnormally fast heart beat** which may indicate an excessive effect of hydrochlorothiazide (contained in Irbesartan/Hydrochlorothiazide tablets)
- if you experience an increased **sensitivity of the skin to the sun** with symptoms of sunburn such as redness, itching, swelling, blistering) occurring more quickly than normal
- if you are **going to have an operation** (surgery) or **be given anaesthetics**
 - if you have **changes in your vision or pain in one or both of your eyes** while taking Irbesartan/Hydrochlorothiazide. This could be a sign that you are developing glaucoma, increased pressure in your eye(s). You should discontinue Irbesartan/Hydrochlorothiazide treatment and seek medical attention.

The hydrochlorothiazide contained in this medicine could produce a positive result in an anti-doping test.

Other medicines and Irbesartan/Hydrochlorothiazide tablets

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

Diuretic agents such as hydrochlorothiazide contained in Irbesartan/Hydrochlorothiazide tablets may have an effect on other medicines. Preparations containing lithium should not be taken with Irbesartan/Hydrochlorothiazide tablets without close supervision by your doctor.

Your may need to have blood checks if you take:

- potassium supplements
- salt substitutes containing potassium
- potassium sparing medicines or other diuretics (water tablets)
- some laxatives
- medicines for the treatment of gout
- therapeutic vitamin D supplements
- medicines to control heart rhythm
- medicines for diabetes (oral agents or insulins)
- carbamazepine (a medicine for the treatment of epilepsy).

It is also important to tell your doctor if you are taking other medicines to reduce your blood pressure, steroids, medicines to treat cancer, pain killers, arthritis medicines, or colestyramine and colestipol resins for lowering blood cholesterol.

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/Hydrochlorothiazide tablets” and “Warnings and precautions”)

Irbesartan/Hydrochlorothiazide tablets with food and drink

Irbesartan/Hydrochlorothiazide tablets can be taken with or without food.

Due to the hydrochlorothiazide contained in Irbesartan/Hydrochlorothiazide tablets, if you drink alcohol while on treatment with this medicine you may have an increased feeling of dizziness on standing up, especially when getting up from a sitting position.

Pregnancy, breast-feeding and fertility

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/Hydrochlorothiazide tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Irbesartan/Hydrochlorothiazide tablets. Irbesartan/Hydrochlorothiazide tablets are not recommended during 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/Hydrochlorothiazide tablets are 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. Irbesartan/Hydrochlorothiazide 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/ Hydrochlorothiazide tablets contain 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 Irbesartan/Hydrochlorothiazide tablets

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

Dosage

Irbesartan/Hydrochlorothiazide tablets are available in three strengths: 150mg/12.5mg, 300mg/12.5mg and 300mg/25mg Film-coated Tablets.

The recommended dose of Irbesartan/Hydrochlorothiazide 150mg/12.5mg tablets is one or two tablets a day.

The recommended dose of Irbesartan/Hydrochlorothiazide 300mg/12.5mg tablets and Irbesartan/Hydrochlorothiazide 300mg/25mg tablets is one tablet a day.

Irbesartan/Hydrochlorothiazide tablets will usually be prescribed by your doctor when your previous treatment did not reduce your blood pressure enough.

Your doctor will instruct you how to switch from the previous treatment to Irbesartan/Hydrochlorothiazide tablets.

Method of administration

Irbesartan/Hydrochlorothiazide tablets are **for oral use**. Swallow the tablet with a sufficient amount of fluid (e.g. one glass of water). You can take Irbesartan/Hydrochlorothiazide 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/Hydrochlorothiazide tablets until your doctor tells you otherwise.

The maximal blood pressure lowering effect should be reached 6-8 weeks after beginning treatment.

Children should not take Irbesartan/Hydrochlorothiazide tablets

Irbesartan/Hydrochlorothiazide 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/Hydrochlorothiazide tablets than you should

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

If you forget to take Irbesartan/Hydrochlorothiazide 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, this medicine can cause side effects, although not everybody gets them.

Some of these effects may be serious and may require medical attention.

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 the above symptoms or get short of breath, stop taking Irbesartan/Hydrochlorothiazide tablets and contact your doctor immediately.

Side effects reported in clinical studies for patients treated with Irbesartan/Hydrochlorothiazide tablets were:

Common side effects (affect 1 to 10 users in 100)

- nausea/vomiting
- abnormal urination
- fatigue
- dizziness (including when getting up from a lying or sitting position)
- blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatine kinase) or raised levels of substances that measure kidney function (blood urea nitrogen, creatinine).

If any of these side effects causes you problems, talk to your doctor.

Uncommon side effects (affect 1 to 10 users in 1000)

- diarrhoea
- low blood pressure
- fainting
- heart rate increased
- flushing
- swelling
- sexual dysfunction (problems with sexual performance)
- blood tests may show lowered levels of potassium and sodium in your blood

If any of these side effects causes you problems, talk to your doctor.

Side effects reported since the launch of Irbesartan/Hydrochlorothiazide tablets

Some undesirable effects have been reported since marketing of Irbesartan/Hydrochlorothiazide tablets. Undesirable effects where the frequency is not known are: headache, ringing in the ears, cough, taste disturbance, indigestion, pain in joints and muscles, liver function abnormal and impaired kidney function, increased level of potassium in your blood and allergic reactions such as rash, hives, swelling of the face, lips, mouth, tongue or throat. Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.

As for any combination of two active substances, side effects associated with each individual component cannot be excluded.

Side effects associated with irbesartan alone

In addition to the side effects listed above, chest pain has also been reported.

Side effects associated with hydrochlorothiazide alone

Loss of appetite; stomach irritation; stomach cramps; constipation; jaundice (yellowing of the skin and/or whites of the eyes); inflammation of the pancreas characterised by severe upper stomach pain, often with nausea and vomiting; sleep disorders; depression; blurred vision; lack of white blood cells, which can result in frequent infections, fever; decrease in number of platelets (a blood cell essential for the clotting of the blood), decreased number of red blood cells (anaemia) characterised by tiredness, headaches, being short of breath when exercising, dizziness and looking pale; kidney disease; lung problems including pneumonia or build-up of fluid in the lungs; increased sensitivity of the skin to the sun; inflammation of blood vessels; a skin disease characterized by the peeling of the skin all over the body; cutaneous lupus erythematosus, which is identified by a rash that may appear on the face, neck, and scalp; allergic reactions; weakness and muscle spasm; altered heart rate; reduced blood pressure after a change in body position; swelling of the salivary glands; high sugar levels in the blood; sugar in the urine; increases in some kinds of blood fat, high uric acid levels in the blood, which may cause gout.

It is known that side effects associated with hydrochlorothiazide may increase with higher doses of hydrochlorothiazide.

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 Irbesartan/Hydrochlorothiazide tablets

Keep this medicine out of the sight and reach of children.

Do not use Irbesartan/Hydrochlorothiazide tablets after the expiry date which is stated on the label after (EXP). The expiry date refers to the last day of that month.

This medicine 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 to protect the environment.

6. Contents of the pack and other information

What Irbesartan/Hydrochlorothiazide contains

Irbesartan/Hydrochlorothiazide Tablets contains two active ingredients: Irbesartan and Hydrochlorothiazide.

Irbesartan/Hydrochlorothiazide 150mg/12.5mg Tablets

Each Irbesartan/Hydrochlorothiazide 150mg/12.5mg Film-coated Tablets contains 150 mg Irbesartan and 12.5 mg of Hydrochlorothiazide.

The other ingredients are:

Tablet Core: Lactose monohydrate, Microcrystalline Cellulose, Croscarmellose Sodium, Hypromellose, Silica Colloidal Anhydrous, Magnesium Stearate

Tablet Coating: Hypromellose, Titanium Dioxide (E171), Macrogol, Talc, Iron Oxide Red (E172), Iron Oxide Black (E172).

Irbesartan/Hydrochlorothiazide 300mg/12.5mg Tablets

Each Irbesartan/Hydrochlorothiazide 300mg/12.5mg Film-coated Tablets contains 300 mg Irbesartan and 12.5 mg of Hydrochlorothiazide.

The other ingredients are:

Tablet Core: Lactose monohydrate, Microcrystalline Cellulose, Croscarmellose Sodium, Hypromellose, Silica Colloidal Anhydrous, Magnesium Stearate, Iron Oxide Yellow (E172)

Tablet Coating: Hypromellose, Titanium Dioxide (E171), Macrogol, Talc, Iron Oxide Yellow (E172).

Irbesartan/Hydrochlorothiazide 300mg/25mg Tablets

Each Irbesartan/Hydrochlorothiazide 300mg/25mg Film-coated Tablets contains 300 mg Irbesartan and 25 mg of Hydrochlorothiazide.

The other ingredients are:

Tablet Core: Lactose monohydrate, Microcrystalline Cellulose, Croscarmellose Sodium, Hypromellose, Silica Colloidal Anhydrous, Magnesium Stearate

Tablet Coating: Hypromellose, Titanium Dioxide (E171), Macrogol, Talc, Iron Oxide Red (E172), Iron Oxide Black (E172).

What Irbesartan/Hydrochlorothiazide tablets looks like and contents of the pack

- Irbesartan/Hydrochlorothiazide 150mg/12.5mg Film-coated Tablets are pink to red coloured, film coated, oval shaped tablets debossed with 'IH 1' on one side and plain on the other side.
- Irbesartan/Hydrochlorothiazide 300mg/12.5mg Film-coated Tablets are yellow coloured, film coated, oval shaped tablets debossed with 'IH 3' on one side and plain on the other side.
- Irbesartan/Hydrochlorothiazide 300mg/25mg Film-coated Tablets are pink to red coloured, film coated, oval shaped tablets debossed with 'IH 2' on one side and plain on the other side

They are supplied in the blister packs containing 7, 10, 14, 15, 20, 28, 30, 49, 50, 56, 60, 84, 90, 98 and 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Ranbaxy Ireland Limited
Spafield, Cork Road,
Cashel, Co. Tipperary
Ireland

Manufacturer:

Ranbaxy Ireland Limited
Spafield, Cork Road,
Cashel, Co,Tipperary
Ireland

BASICS GmbH
Hemmelrather weg 201, D-51377 Leverkusen
Germany

TERAPIA S.A.
124 Fabricii Street, 400 632 Cluj Napoca
Romania

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

DE	IRBESARTAN COMP BASICS 150mg/12,5mg, 300mg/12,5mg, 300mg/25mg Filmtableten
EL	Irbesartan hydrochlorothiazide Ranbaxy 150mg/12.5mg, 300mg/12.5mg, 300mg/25mg επικαλυμμένα με λεπτό υμένιο δισκία
FR	IRBESARTAN HYDROCHLOROTHIAZIDE RANBAXY 150mg/12,5mg, 300mg/12,5mg, 300mg/25mg, comprimé pelliculé
IE	Irbesartan/Hydrochlorothiazide 150mg/12.5mg, 300mg/12.5mg, 300mg/25mg Film-Coated Tablets
RO	Irbesartan Hidroclorotiazidă Ranbaxy 150mg/12.5mg, 300mg/12.5mg, 300mg/25mg comprimate filmate
UK	Irbesartan Hydrochlorothiazide Ranbaxy 150/12.5mg, 300/12.5mg, 300/25mg Film-coated Tablets

This leaflet was last revised in September 2014