

PACKAGE LEAFLET

Package leaflet: Information for the user

Irbesartan/Hydrochlorothiazide Brown & Burk 150mg/12.5mg, 300mg/25mg and 300mg/12.5mg Film-coated tablets irbesartan/hydrochlorothiazide

Read all of these 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.

The full name of this product is Irbesartan /Hydrochlorothiazide 150mg/12.5mg, 300mg/12.5mg and 300mg/25mg Film-coated Tablets but within the leaflet it will be referred to as Irbesartan /Hydrochlorothiazide tablets.

What is in this leaflet

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

Irbesartan/Hydrochlorothiazide tablets 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 is 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 tablets 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 containing aliskiren

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 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 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, ramipiril) in particular if you have diabetes-related kidney problems.
 - aliskiren
- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while using Irbesartan/Hydrochlorothiazide tablets.
- If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking irbesartan/hydrochlorothiazide, seek medical attention immediately.

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 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).

You should also tell your doctor if you:

- are on a **low-salt diet**
- 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)
- 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
- are **going to have an operation** (surgery) or **be given anaesthetics**
- experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to a week of taking Irbesartan Hydrochlorothiazide. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy,

you can be at higher risk of developing this. You should discontinue Irbesartan/Hydrochlorothiazide tablets treatment and seek medical attention.

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

Children and adolescents

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

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 the 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 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”).

You 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 as repaglinide 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.

Irbesartan/Hydrochlorothiazide tablets with food, drink and alcohol

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 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/Hydrochlorothiazide tablets are not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

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 medicine.

Driving and using machines

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.

Information on sodium content

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

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

The recommended dose is one 150mg/12.5mg, 300mg/12.5mg or 300mg/25mg tablet a day or two 150mg/12.5mg or 300mg/12.5mg tablets 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 tablets 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.

If you take more Irbesartan/Hydrochlorothiazide tablets than you should

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

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 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.

Serious side effects

Rare cases of allergic skin reactions (rash, urticarial), 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.

Other side effects

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

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

- 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 (may affect up to 1 in 100 people):

- diarrhea
- 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 the marketing of Irbesartan hydrochlorothiazide tablets.

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

Cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.

Frequency not known (cannot be estimated from the available data) : 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.

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,

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

- chest pain,

Frequency not known (can not be estimated from the available data):

- decrease in the number of platelets (a blood cell essential for the clotting of the blood) have also been reported.
- decreased number of red blood cells (anaemia – symptoms may include tiredness, headaches, being short of breath when exercising, dizziness and looking pale)
- severe allergic reactions (anaphylactic shock).
- low blood sugar levels have also been reported.

Side effects associated with hydrochlorothiazide alone

Frequency not known (cannot be estimated from the available data):

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; Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma), lack of white blood cells, which can result in frequent infections, fever; decrease in the 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; skin and lip cancer (Non-melanoma skin cancer).

Very rare: Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 this medicine after the expiry date which is stated on carton or blister after EXP. The expiry date refers to the last day of that month.

PVC/ACLAR-Aluminium blister packaging:

Do not store above 30° C.

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 Irbesartan /Hydrochlorothiazide tablets contain

- The active substances are irbesartan and hydrochlorothiazide.
 - Each Irbesartan/Hydrochlorothiazide 150mg/12.5mg film-coated tablet contains 150mg of irbesartan and 12.5mg hydrochlorothiazide.
 - Each Irbesartan/Hydrochlorothiazide 300mg/12.5mg film-coated tablet contains 300mg of irbesartan and 12.5mg of hydrochlorothiazide.
 - Each Irbesartan/Hydrochlorothiazide 300mg/25mg film-coated tablet contains 300mg of irbesartan and 25mg of hydrochlorothiazide.

The other ingredients are:

Tablet core:

150mg/ 12.5 mg and 300mg/ 25 mg film-coated tablets

mannitol, sodium starch glycolate Type B, povidone K 30, polysorbate 80, Hypromellose 2910 5cps, silica colloidal anhydrous, magnesium stearate

300mg/ 12.5 mg film-coated tablets

mannitol, sodium starch glycolate Type B, povidone K 30, polysorbate 80, Hypromellose 2910 5cps, silica colloidal anhydrous, magnesium stearate, iron oxide red, iron oxide yellow

Film-coat:

150mg/ 12.5 mg and 300mg/ 12.5 mg film-coated tablets

Hypromellose 2910, titanium dioxide, macrogol 3350, carnauba wax, iron oxide yellow and iron oxide red

300mg/ 25 mg film-coated tablets

Hypromellose 2910, titanium dioxide, macrogol 3350, iron oxide red; carnauba wax and black iron oxide.

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

Irbesartan/Hydrochlorothiazide 150 mg/12.5 mg film-coated Tablets are Peach coloured, capsule shaped, biconvex, film-coated tablets, approximately 14 mm long and 7 mm wide, debossed with 'IH' on one face and plain on other face.

Irbesartan/Hydrochlorothiazide 300 mg/25 mg film-coated Tablets are Brick red coloured, capsule shaped, biconvex, film-coated tablets, approximately 18 mm long and 9 mm wide, debossed with 'IH1' on one face and plain on other face.

Irbesartan/Hydrochlorothiazide 300 mg/12.5 mg film-coated Tablets are Peach coloured, capsule shaped, biconvex, film-coated tablets, approximately 18 mm long and 9 mm wide debossed with 'IH2' on one face and plain on other face.

Pack contents are 10, 14, 28, 30, 56, 84, 90 and 98 tablets in PVC/ACLAR/Aluminium blisters or Aluminium-Aluminium blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in **02/2022**