

Package leaflet: Information for the patient

Irbesartan/Hydrochlorothiazide 150 mg/12.5 mg tablets **Irbesartan/Hydrochlorothiazide 300 mg/12.5 mg tablets** **Irbesartan/Hydrochlorothiazide 300 mg/25 mg tablets**

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

1. What Irbesartan/Hydrochlorothiazide is and what it is used for

Irbesartan/Hydrochlorothiazide 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 work together to lower blood pressure further than if either was given alone.

Irbesartan/Hydrochlorothiazide 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

Do not take Irbesartan/Hydrochlorothiazide:

- 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 your doctor determines that you have **persistently high calcium or low potassium levels in your blood**
- **if you have diabetes mellitus or impaired kidney function** and you are treated with a blood lowering medicine called aliskiren.

Warnings and precautions

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

- 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.
- 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 taking Irbesartan/Hydrochlorothiazide
- if you get **excessive vomiting or diarrhoea**
- if you suffer from **kidney problems, including narrowing of the kidney artery** or have had a **kidney transplant**
- if you suffer from **heart problems, including a narrowing of the valves in the heart, an enlarged heart muscle** or a **weakness of the heart muscle** (heart failure)
- if you have a **narrowing of the heart blood vessels**, which may cause chest pain e.g. angina
- if you suffer from **other 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 have a history of **allergies** or **asthma**
- 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 on a **low-salt diet**
- if you are taking **diuretics (water tablets)**
- 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.

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

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”

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

Irbesartan/Hydrochlorothiazide 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).

During treatment

You should also tell your doctor:

- 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)

- 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 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 weeks 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.
- if you need to have a **blood test** to check how the **parathyroid** (a gland which helps maintain calcium levels) is working, tell the doctor or hospital staff you are taking this medicine.

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

Children and adolescents

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

Other medicines and Irbesartan/Hydrochlorothiazide

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 may have an effect on other medicines.

Preparations containing lithium (used to treat mental health problems) should not be taken with Irbesartan/Hydrochlorothiazide 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” 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 e.g. probenecid, sulfinpyrazone
- therapeutic vitamin D or calcium supplements
- medicines to control heart rhythm e.g. digoxin
- medicines for diabetes (oral agents as repaglinide or insulins)
- carbamazepine (a medicine for the treatment of epilepsy)
- amphotericin (a medicine used to treat fungal infections)
- penicillin G-sodium (an antibiotic used to treat bacterial infections).
- carbenoxolone (used for stomach and mouth ulcers)
- medicines that may increase levels of potassium in your blood e.g. heparin (used to prevent blood clots)

It is also important to tell your doctor if you are taking other medicines to reduce your blood pressure, steroids, medicines to treat cancer e.g. cyclophosphamide, methotrexate, pain killers known as NSAIDs or ‘COX-2’ inhibitors e.g. celecoxib or acetylsalicylic acid, amantadine (a medicine used to

treat Parkinsons disease or influenza), allopurinol for gout, medicines that effect stomach emptying e.g. atropine, biperiden or colestyramine and colestipol resins for lowering blood cholesterol.

Irbesartan/Hydrochlorothiazide with alcohol

Due to the hydrochlorothiazide contained in Irbesartan/Hydrochlorothiazide, 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 and breast-feeding

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 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. Irbesartan/Hydrochlorothiazide is 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 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

No studies on the effects on the ability to drive and use machines have been performed. Irbesartan/Hydrochlorothiazide 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 to drive or use machines.

Irbesartan/Hydrochlorothiazide contains lactose and sodium

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.

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

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 dose of Irbesartan/Hydrochlorothiazide is one tablet a day. Irbesartan/Hydrochlorothiazide 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.

Method of administration

Irbesartan/Hydrochlorothiazide is for **oral use**. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take Irbesartan/Hydrochlorothiazide 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 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 than you should

If you accidentally take too many tablets, contact your doctor immediately. You may feel dizzy, weak, feel your heart beating faster or slower, sick and sleepy or drowsy.

Children should not take Irbesartan/Hydrochlorothiazide

Irbesartan/Hydrochlorothiazide 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

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. **If you notice any of the following side effects, stop taking Irbesartan/Hydrochlorothiazide and contact your doctor or go to the nearest hospital casualty department straight away:**

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

- yellowing of the skin and whites of the eyes

Not known (frequency cannot be estimated from the available data):

- rare cases of allergic skin reactions (rash, urticaria), as well as localised swelling of the face, lips and/or tongue and difficulty breathing.
- heart beat is faster and uneven or feeling of skipped heart beat (palpitations), pounding in chest, feeling faint and dizzy, which may be caused by problems with the heart rhythm. This can be detected by ECG (a test used to show how the heart is beating).
- an increase in number of infections that you get e.g. sore throat, mouth ulcers, or looking pale, feeling tired, breathless, especially after exercise, bruising or bleeding more easily, which may be due to a reduction in the number or type of blood cells in the blood. This may be caused by a problem with the bone marrow (where blood cells are produced).
- paleness, feeling tired or breathless, which may be caused by the breakdown of red blood cells.
- 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)
- pain and difficulty when breathing, fever, chest pain and cough, caused by fluid on the lungs (pulmonary oedema).
- passing water more often, in greater amounts which is pale in colour, or straining or being unable to pass water or less often, which may be darker in colour or may be bloody. This may be due to problems with the kidneys.
- severe upper stomach pain and feeling and being sick, which may be due to liver problems.
- rash with raised purple spots and flat red areas caused by inflammation of the blood vessels (vasculitis).
- a serious allergic skin reaction, which includes rash with flat red areas, blistering and large areas of peeling skin all over the body.
- cutaneous lupus erythematosus - you may notice a rash that may appear on the face, neck and scalp.
- increased sensitivity of the skin to the sun.

- inflammation of the pancreas - you may have severe stomach pain that radiates round to the back and feeling or being sick.
- skin and lip cancer (Non-melanoma skin cancer)

Other possible side effects

Side effects reported in clinical studies for patients treated with irbesartan/hydrochlorothiazide combination tablets were:

Common (may affect up to in 10 people):

- feeling sick/being sick (nausea/vomiting)
- feeling tired (fatigue)
- dizziness
- blood tests may show raised levels of an enzyme that measures how the muscles and heart are working (creatinine kinase) or raised levels of substances that measure how the kidney is working (blood urea nitrogen, creatinine).

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

- 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
- feeling dizzy after getting up from a lying or sitting position

Not known (frequency cannot be estimated from the available data):

- headache
- ringing in the ears
- cough
- taste disturbance, indigestion
- pain in joints and muscles
- blood tests may show that the liver is not working properly
- blood tests may show increased level of potassium in your blood.

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

Side effects associated with irbesartan alone

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

- chest pain

Rare (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.

Not known (frequency cannot be estimated from the available data):

- bruising and bleeding more easily which may be caused by a reduced number of platelets (blood clotting cells) tiredness, headaches, being short of breath when exercising or dizziness and looking pale which may be caused by a reduced number of red blood cells (anaemia)
- low blood sugar levels
- severe allergic reactions (anaphylactic shock)

Side effects associated with hydrochlorothiazide alone

Very rare (may affect up to 1 in 10,000 people):

- acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion)

Not known (frequency cannot be estimated from the available data):

- Loss of appetite
- stomach irritation, stomach cramps, constipation
- sleep disorders
- depression
- blurred vision, colour vision affected with objects appearing more yellow than they are (xanthopsia), short-sightedness (acute myopia)
- fever
- weakness and muscle spasm
- tingling, pricking or burning feelings of skin “pins and needles” (paresthesia)
- restlessness, light-headedness
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Irbesartan/Hydrochlorothiazide

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, label or blister after EXP. The expiry date refers to the last day of that month.

The in-use shelf-life of the product when stored in bottles is 90 days once opened.

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 protect the environment.

6. Contents of the pack and other information

What Irbesartan/Hydrochlorothiazide contains

Irbesartan/Hydrochlorothiazide Mylan 150 mg/12.5 mg tablets

- The active substances are irbesartan and hydrochlorothiazide. Each 150 mg/12.5 mg tablet contains 150 mg of irbesartan and 12.5 mg of hydrochlorothiazide.

- The other ingredients are: cellulose microcrystalline (E460), silica, colloidal anhydrous, sodium laurilsulfate, pregelatinised starch (maize), magnesium stearate (E470b), povidone (K-90), lactose monohydrate, croscarmellose sodium. See section 2, ‘Irbesartan/Hydrochlorothiazide contains lactose and sodium’.

Irbesartan/Hydrochlorothiazide Mylan 300 mg/12.5 mg tablets

- The active substances are irbesartan and hydrochlorothiazide. Each 300 mg/12.5 mg tablet contains 300 mg of irbesartan and 12.5 mg of hydrochlorothiazide.
- The other ingredients are: cellulose microcrystalline (E460), silica, colloidal anhydrous, sodium laurilsulfate, pregelatinised starch (maize), magnesium stearate (E470b), povidone (K-90), lactose monohydrate, croscarmellose sodium, quinoline yellow (E104). See section 2, ‘Irbesartan/Hydrochlorothiazide Mylan contains lactose and sodium’.

Irbesartan/Hydrochlorothiazide Mylan 300 mg/25 mg tablets

- The active substances are irbesartan and hydrochlorothiazide. Each 300 mg/25 mg tablet contains 300 mg of irbesartan and 25 mg of hydrochlorothiazide. The other ingredients are: cellulose microcrystalline (E460), silica, colloidal anhydrous, sodium laurilsulfate, pregelatinised starch (maize), magnesium stearate (E470b), povidone (K-90), lactose monohydrate, croscarmellose sodium. See section 2, ‘Irbesartan/Hydrochlorothiazide Mylan contains lactose and sodium’.

What Irbesartan/Hydrochlorothiazide looks like and contents of the pack

Irbesartan/Hydrochlorothiazide 150 mg/12.5 mg tablets are white to off white, oval, biconvex tablets debossed with “M” on one side of the tablet and “I33” on the other side

Irbesartan/Hydrochlorothiazide 300 mg/12.5 mg tablets are light-yellow, oval, biconvex tablets debossed with “M” on one side of the tablet and “I34” on the other side.

Irbesartan/Hydrochlorothiazide 300 mg/25 mg tablets are white to off white, oval, biconvex tablets debossed with “M” on one side of the tablet and “I35” on the other side.

Irbesartan/Hydrochlorothiazide is available in blisters of 14, 28, 30, 56, 90, 98, 100 tablets, blister unit-dose of 56 x 1 tablets, calendar pack of 28 tablets and in bottles of 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer:

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

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This leaflet was last revised in 01/2025.