

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/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 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 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 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 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 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 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.

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.

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).

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)
- 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 symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or a sign that you are developing glaucoma, increased pressure in your eye(s), 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. 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.

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 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
- 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, and medicines to treat cancer, pain killers, arthritis medicines or colestyramine and colestipol resins for lowering blood cholesterol.

Irbesartan/Hydrochlorothiazide with food, drink and alcohol

Irbesartan/Hydrochlorothiazide can be taken with or without food.

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, specially 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

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 sodium

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


3. How to take Irbesartan/Hydrochlorothiazide


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

Dosage of Irbesartan/Hydrochlorothiazide

150 mg/12.5 mg

The recommended dose of Irbesartan/Hydrochlorothiazide 150 mg/12.5 mg is one tablet a day. Irbesartan/Hydrochlorothiazide 150 mg/12.5 mg 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. If this dose does not help to reduce your blood pressure as required, the doctor may prescribe Irbesartan/Hydrochlorothiazide 300 mg/12.5 mg to you.

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Dosage of Irbesartan/Hydrochlorothiazide 300 mg/12.5 mg

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

Irbesartan/Hydrochlorothiazide 300 mg/12.5 mg 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.

If this dose does not help to reduce your blood pressure as required, the doctor may prescribe Irbesartan/ Hydrochlorothiazide 300 mg/25 mg to you.

Dosage of Irbesartan/Hydrochlorothiazide 300 mg/25 mg

The recommended dose of Irbesartan/Hydrochlorothiazide 300 mg/25 mg is one tablet a day. This dose should not be increased. Irbesartan/Hydrochlorothiazide 300 mg/25 mg 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. If this medicine does not help to reduce your blood pressure as required, the doctor will prescribe additional treatment to you.

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.

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.

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 and contact your doctor immediately.



The frequency of the side effects listed below is defined using the following convention:

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

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

Side effects reported in clinical studies for patients treated with Irbesartan/Hydrochlorothiazide 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)
- 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.

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

Uncommon side effects (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.

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

Side effects reported since the launch of the combination of Irbesartan and Hydrochlorothiazide

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

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.

Side effects associated with hydrochlorothiazide alone

Skin and lip cancer (non-melanoma skin cancer); 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. **Very rare side effects** (may affect up to 1 in 10,000 people): 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, Website: <https://yellowcard.mhra.gov.uk/> 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

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 packaging 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 protect the environment.

6. Contents of the pack and other information

What Irbesartan/Hydrochlorothiazide contains

- The active substances are irbesartan and hydrochlorothiazide.

Each Irbesartan/Hydrochlorothiazide 150 mg/12.5 mg film-coated tablet contains 150 mg irbesartan (as irbesartan hydrochloride) and 12.5 mg hydrochlorothiazide.

Each Irbesartan/Hydrochlorothiazide 300 mg/12.5 mg film-coated tablet contains 300 mg irbesartan (as irbesartan hydrochloride) and 12.5 mg hydrochlorothiazide.

Each Irbesartan/Hydrochlorothiazide 300 mg/25 mg film-coated tablet contains 300 mg irbesartan (as irbesartan hydrochloride) and 25 mg hydrochlorothiazide.

- The other ingredients are: Irbesartan/Hydrochlorothiazide 150 mg/12.5 mg: mannitol, hydroxypropylcellulose, low-substituted hydroxypropylcellulose, sodium starch glycolate, talc, macrogol 6000, hydrogenated castor oil in the tablet core and polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, yellow iron oxide (E172) and red iron oxide (E172) in the film-coating. See section 2 "Irbesartan/ Hydrochlorothiazide contains sodium".

Irbesartan/Hydrochlorothiazide 300 mg/12.5 mg: mannitol, hydroxypropylcellulose, low-substituted hydroxypropylcellulose, sodium starch glycolate, talc, macrogol 6000, hydrogenated castor oil in the tablet core and polyvinyl alcohol, titanium dioxide (E171), macrogol, talc in the film-coating. See section 2 "Irbesartan/ Hydrochlorothiazide contains sodium".

Irbesartan/Hydrochlorothiazide 300 mg/25 mg: mannitol, hydroxypropylcellulose, low-substituted hydroxypropylcellulose, sodium starch glycolate, talc, macrogol 6000, hydrogenated castor oil in the tablet core and polyvinyl alcohol, titanium dioxide (E171), macrogol,

talc, yellow iron oxide (E172) and red iron oxide (E172) in the film-coating. See section 2 "Irbesartan/ Hydrochlorothiazide contains sodium".

What Irbesartan/Hydrochlorothiazide looks like and contents of the pack

Irbesartan/Hydrochlorothiazide 150 mg/12.5 mg Pale pink, biconvex, oval, film-coated tablets (tablets).

Irbesartan/Hydrochlorothiazide 300 mg/12.5 mg White, biconvex, capsule shaped, film-coated tablets (tablets).

Irbesartan/Hydrochlorothiazide 300 mg/25 mg Pale pink, biconvex, capsule shaped, film-coated tablets (tablets).

Boxes of 14, 28, 30, 56, 56 x 1, 84, 90 and 98 film-coated tablets in blisters are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer

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