

IRBEJUB H[®]

Irbesartan and Hydrochlorothiazide Tablets 150 mg + 12.5 mg, 300 mg + 12.5 mg, 300 mg + 25 mg)

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What is Irbejub H is used for

Irbejub H is used to treat high blood pressure when treatment with irbesartan or hydrochlorothiazide alone did not provide adequate control of your blood pressure.

How Irbejub H works

Irbejub H 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 increases the amount of water you lose in your urine and so causes a lowering of blood pressure. The two active ingredients in Irbejub H work together to lower blood pressure further than if either was given alone.

Before you use Irbejub H

- When you must not use it

Do not take this medicine if:

- if you are allergic to irbesartan, or to any of the other ingredients of this medicine (listed in Product Description).
- if you are allergic to hydrochlorothiazide, or to any other sulfonamide-derived medicines (listed in Product Description).
- if you are more than 3 months pregnant. (It is also better to avoid Irbejub H in early pregnancy – see Pregnancy and Breast-feeding 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 mellitus or impaired kidney function and you are treated with aliskiren (another medicine to treat high blood pressure).

Irbejub H should not be given to children and adolescents (under 18 years).

- Before you start to use it

Irbejub H 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 medicine.

Irbejub H contains sodium. This medicine contains less than 1 mmol sodium per tablet, that is to say essentially 'sodium-free'.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

Your doctor will normally advise you to stop taking Irbejub H before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Irbejub H. Irbejub H 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. Irbejub H 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.

Taking other medications:

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket, or health food shop.

Diuretic agents such as the hydrochlorothiazide contained in Irbejub H may have an effect on other medicines.

Preparations containing lithium should not be taken with Irbejub H 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 Irbejub H" and "Things you must do").

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.

Taking Irbejub H with food and drink: Irbejub H can be taken with or without food.

Due to the hydrochlorothiazide contained in Irbejub H, 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.

How to use Irbejub H

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Dose titration with the individual components (i.e. irbesartan and hydrochlorothiazide) may be recommended.

When clinically appropriate direct change from monotherapy to the fixed combinations may be considered:

- Irbesartan and Hydrochlorothiazide

tablet 150 mg/12.5 mg may be administered in patients whose blood pressure is not adequately controlled with hydrochlorothiazide or irbesartan 150 mg alone;

- Irbesartan and Hydrochlorothiazide tablet 300 mg/12.5 mg may be administered in patients insufficiently controlled by irbesartan 300 mg or by Irbesartan and Hydrochlorothiazide tablet 150 mg/12.5 mg.
- Irbesartan and Hydrochlorothiazide tablets 300 mg/25 mg may be administered in patients insufficiently controlled by Irbesartan and Hydrochlorothiazide tablets 300 mg/12.5 mg.
- Doses higher than 300 mg irbesartan and 25 mg hydrochlorothiazide once daily are not recommended.

When necessary, Irbesartan and Hydrochlorothiazide tablet may be administered with another antihypertensive medicinal product.

Renal impairment due to the hydrochlorothiazide component, Irbesartan and Hydrochlorothiazide tablet is not recommended for patients with severe renal dysfunction (creatinine clearance < 30 ml/min). Loop diuretics are preferred to thiazides in this population. No dosage adjustment is necessary in patients with renal impairment whose renal creatinine clearance is ≥ 30 ml/min.

Hepatic impairment: Irbesartan and Hydrochlorothiazide tablet is not indicated in patients with severe hepatic impairment. Thiazides should be used with caution in patients with impaired hepatic function. No dosage adjustment of Irbesartan and Hydrochlorothiazide tablet is necessary in patients with mild to moderate hepatic impairment.

Older people: no dosage adjustment of Irbesartan and Hydrochlorothiazide tablet is necessary in older people.

Paediatric patients: Irbesartan and Hydrochlorothiazide tablet is not recommended for use in children and adolescents because the safety and efficacy have not been established. No data are available

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it.

Use Irbejub H for the duration that the doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause hypertension, heartbeat faster than usual, nausea and fatigue

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Irbejub H.

Tell your doctor immediately if you become pregnant while using this medication.

Take Irbejub H only with a doctor's prescription.

Tell your doctor if any of the following apply to you:

- if you get excessive vomiting or diarrhoea
- if you suffer from kidney problems or have had 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 aliskiren.
- if you are taking an ACE-inhibitor (for example enalapril, lisinopril, ramipril) in particular if you have diabetes-related kidney problems.
- if you experience 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 Irbejub H, seek medical attention immediately.

Inform your healthcare providers before taking Irbejub H 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 Irbejub H.

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 Irbejub H)
- 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 Irbejub H. This could be a sign that you are developing glaucoma, increased pressure in your eye(s). You should discontinue Irbejub H treatment and seek medical attention.

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

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Irbejub H to anyone else, even if they have the same symptoms or condition as you.

Children should not take Irbejub H: Irbejub H should not be given to children under 18 years of age. If a child swallows some tablets, contact your doctor immediately.

- Things to be careful of***Driving and using machines:***

No studies on the effects on the ability to drive and use machines have been performed. Irbejub H is unlikely to affect your ability to drive or use machines. However, occasionally dizziness or tiredness may occur during treatment of high blood pressure. If you experience these, talk to your doctor before attempting to drive or use machines

Side effects of Irbejub H

Like all medicines, Irbejub H can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine. 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 these symptoms or get short of breath, stop taking Irbejub H and contact your doctor immediately.

Other side effects reported in clinical studies for patients treated with Irbejub H were:

Common

- 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 (creatin kinase) or raised levels of substances that measure kidney function (blood urea nitrogen, creatinine).

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

Uncommon

- diarrhea
- low blood pressure
- fainting
- heart rate increased
- 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 Irbejub H. Some undesirable effects have been reported since marketing of Irbejub

H.

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, choroidal effusion, acute myopia and acute angle-closure glaucoma. 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.

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 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, acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion). Frequency ‘not known’: Skin and lip cancer (Non-melanoma skin cancer); 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).

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Irbejub H**- Storage**

Keep out of the reach of children.

Store below 30°C.

Store in the original package in order to protect from moisture. Do not use Irbejub H after the expiry date which is stated on the carton and on the blister after expiry

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description**- What it looks like**

For 150 mg+12.5 mg:

Peach coloured, biconvex, oval shaped film-coated tablets, debossed with ‘450’ on one side and plain on the other.

For 300 mg+12.5 mg:

Peach coloured, biconvex, oval shaped film-coated tablets, debossed with ‘451’ on one side and plain on the other.

For 300 mg+25 mg:

Dark pink coloured, biconvex, oval shaped film-coated tablets, debossed with '452' on one side and plain on the other.

Ingredients

• Active ingredient(s)

Each film-coated tablet contains:
Irbesartan 150 mg and
Hydrochlorothiazide 12.5 mg
Irbesartan Ph. Eur, 300 mg and
Hydrochlorothiazide Ph. Eur,
12.5 mg

Irbesartan Ph. Eur, 300 mg and
Hydrochlorothiazide Ph. Eur, 25 mg

• Inactive ingredient(s)

Lactose Monohydrate, Microcrystalline
Cellulose, Pregelatinized Starch,
Croscarmellose Sodium, Povidone,
Magnesium Stearate, Ferric Oxide Red
(for Irbejub H 300mg+12.5mg), Ferric
Oxide Yellow (for Irbejub H
300mg+12.5mg), Opadry II pink
32F84835 (for Irbejub H
150mg+12.5mg and 300mg+12.5mg),
Opadry II 31F86925 Brown (for
Irbejub H 300mg+25mg) and Purified
water.

MAL number

For 150mg+12.5mg:
MAL20046104AZ

For 300mg+12.5mg:
MAL20046105AZ

For 300mg+25mg:
MAL20046106AZ

Manufacturer

Jubilant Generics Limited,
Village Sikandarpur Bhainswal,
Roorkee- Dehradun Highway,
Bhagwanpur, Roorkee, District -
Haridwar, Uttarakhand 247661, India.

Product Registration Holder

Pharmaniaga Marketing Sdn. Bhd. No.
7, Lorong Keluli 1B, Kawasan
Perindustrian Bukit Raja Selatan,
Seksyen 7, 40000 Shah Alam, Selangor
Darul Ehsan.

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