IRB-H ®

(Irbesartan and Hydrochlorothiazide 150 mg /12.5 mg)

Consumer Medication Information Leaflet
(RiMUP)

What is in this leaflet

What *IRB-H* is used for:

IRB-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 *IRB-H works*

IRB-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 causes increased urine output and so causes a lowering of blood pressure.

The two active ingredients in IRB-H work together to lower blood pressure further than if either was given alone.

Before you use *IRB-H*

When you must not take it :

- if you are allergic (hypersensitive) to Irbesartan or any ofthe other ingredients of IRB-H.
- if you are **allergic** (hypersensitive) to hydrochlorothiazideor any other sulfonamide-derived medicines.
- if you are **more than 3 months pregnant**. (It is also better to avoid IRB-H in early pregnancy – see pregnancysection).
- 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** IRB-H should not be given to children and adolescents (under 18years).

Before you Start IRB-H:

IRB-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.

Inform your healthcare providers before taking IRB-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 IRB-H.

Before taking IRB-H, tell your doctor:

- 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 IRB-H, seek medical attention immediately.

Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including Medicines obtained without a prescription. Diuretic agents such as the hydrochlorothiazide contained in IRB-H may have an effect on other medicines. Preparations containing lithium should not be taken with IRB-H without close supervision by your doctor.

You may need to have blood checks if you take:

- Potassium supplements
- Salt substitutes containing Potassium
- Potassium sparing medicines or other diuretics (watertablets)
- Some laxatives
- Medicines for the treatment of gout
- Therapeutic vitamin D supplements
- Medicines to control heart rhythm
- Medicines for diabetes (oral agents or insulins).

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 IRB-H with food and drink

IRB-H can be taken with or without food. Due to the hydrochlorothiazide contained in IRB-H, 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

How to take IRB-H

Always take IRB-H exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How to use IRB-H

How much to use

The usual dose of IRB-H 150 mg/12.5 mg film-coated tablets
is one or two tablets a day.

IRB-H 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 previoustreatment to IRB-H.

When to take & How long to take

IRB-H is for oral use. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take IRB-H 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 IRB-H until your doctor tells you otherwise. The maximal blood pressure lowering effect should be reached 6-8 weeks after beginning treatment.

If you forget to take it

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 forgottendose.

If you take more too much (overdose)

If you accidentally take too many tablets, contact your doctorimmediately.

While you are Using IRB-HThings you must do:

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 a kidneytransplant.
- If you suffer from heart problems
- If you suffer from liver problems.
- If you suffer from diabetes
- If you suffer from lupus erythematous (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).

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

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

Pregnancy:

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking IRB-H before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of IRB-H. IRB-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. IRB-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 new born, or was born prematurely.

Things you must not do

Children should not take IRB-H IRB-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. IRB-H 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.

Side effects:

Like all medicines, IRB-H can cause side effects, although noteverybody 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 localized swelling of the face, lips and/or tongue have been reported in patients taking Irbesartan.

Frequency 'not known':

- *Choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes;*
- *Acute myopia: sudden nearsightedness or blurred vision;*
- *Acute angle-closure glaucoma: a rapid increased pressure in your eyes, eye pain. If left untreated, it may lead to permanent vision loss.*

If you get any of the above symptoms or get short of breath, stop taking IRB-H and contact your doctor immediately. Side effects reported in clinical studies for patients treated with IRB-H were:

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

- Nausea/Vomiting
- Abnormal Urination
- Fatigue
- Dizziness (including when getting up from a lying orsitting 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 yourdoctor.

Uncommon side effects *(affect 1 to 10 user in 1,000)*

- Diarrhoea
- Low blood pressure
- Fainting
- Heart rate increased
- Flushing
- Swelling
- Sexual dysfunction (problem with sexual performance)
- Blood tests lowered levels of potassium and sodium inyour blood.
- Frequency 'not known': Skin and lip cancer (Non melanomaskin cancer).

Very Rare:

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

If any of these side effects causes you problems, talk to yourdoctor**.**

Side effects reported since the launch of IRB-H

Some undesirable effects have been reported since marketing of IRB-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. 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 hydrochlorothiazide alone: Loss of appetite; stomach irritation; stomach cramps;constipation; jaundice (yellowing of the skin and/or whitesof the eyes); inflammation of the pancreas characterized bysevere 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 forthe clotting of the blood), decreased number of red blood cells (anaemia) characterized by tiredness, headaches, being shortof breath when exercising, dizziness and looking pale; kidneydisease; lung problems including pneumonia or build-up offluid in the lungs; increased sensitivity of the skin to the sun; inflammation of blood vessels ; a skin disease characterizedby the peeling of the skin all over the body; cutaneous lupuserythematosus, which is identified by a rash that may appearon the face, neck, and scalp; allergic reactions; weakness and muscle spasm; altered heart rate; reduced blood pressure aftera change in body position; swelling of the salivary glands;high sugar levels in the blood; sugar in the urine; increasesin some kinds of blood fat; high uric acid levels in the blood, which may cause gout.

It is known that side effects associated with hydrochlorothiazidemay 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 by visiting the website npra.gov.my [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of IRB-H:

Keep this medicine out of the sight and reach of children. Store below 30°C.

Disposal:

Do not use IRB-H after the expiry date which is stated on the carton after EXP. Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose off medicines no longer required. These measures will help to protect the environment.

Product Description:

What it look like:

IRB-H 150 mg/12.5 mg film coated tablets:

Peach coloured, film-coated biconvex oval shaped tablets,
debossed with "H 35" on one side and plain on the other side.

Active ingredients:

IRB-H 150 mg/12.5 mg:

Each film coated tablets contains : Irbesartan Ph.Eur.,150 mg
and Hydrochlorothiazide Ph.Eur.,12.5 mg

Inactive Ingredient:

Lactose monohydrate, Sodium starch glycolate (Type A), Povidone, Silica colloidal anhydrous, Talc, Sodium stearyl fumarate.

MAL No.: MAL18056151AZ

Manufactured By

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