

IRBEL HCT

Consumer Medication Information Leaflet (RiMUP)

Irbesartan and Hydrochlorothiazide Tablets
150 + 12.5 mg / 300 + 12.5 mg / 300 + 25 mg Tablets

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What **IRBEL HCT** is used for

IRBEL HCT are used to treat high blood pressure, when treatment with irbesartan or hydrochlorothiazide alone did not provide adequate control of your blood pressure. High blood pressure, if not treated, can damage blood vessels in several organs such as heart, kidneys, brain and eyes. This may lead to heart attack, kidney failure, stroke, or blindness.

How **IRBEL HCT** work

IRBEL HCT is a combination product which contains two active ingredients, irbesartan and hydrochlorothiazide. Irbesartan belongs to a group of medicines called angiotensin-II receptor antagonist and hydrochlorothiazide belongs to a group of medicines called diuretics (water tablets). These medicines are used to lower blood pressure. The angiotensin II receptor antagonist (irbesartan) works by causing blood vessels to relax, which in turn lowers blood pressure. Diuretic (hydrochlorothiazide) works on the kidneys to increase the flow of urine and decrease the amount of water in the body, thereby reducing blood pressure. The two active ingredients work together to lower blood pressure further than if either was given alone. This medicine is available only with a doctor's prescription.

Before you use **IRBEL HCT**

When you must not use it

Do not take IRBEL HCT if you:

- have previously had an allergic reaction to irbesartan or/and hydrochlorothiazide or to sulphonamides derived medicines or to any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.
- are more than 3 months pregnant
- have severe liver or kidney problems
- have persistently high calcium or low potassium levels in your blood
- are currently breast-feeding

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If you are not sure whether you should start taking this medicine talk to your doctor.

Before you start to use it

Inform your healthcare providers before taking **IRBEL HCT** 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 **IRBEL HCT**. Before taking **IRBEL HCT**, 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 **IRBEL HCT** seek medical attention immediately.

Tell your doctor if you have or have had any of the following medical conditions:

- You suffer or have recently suffered from excessive vomiting and/or diarrhoea.
- You have been recently treated with

high dose of water tablets (diuretics) or are on a restricted salt diet.

- You have problems with your kidney(s) including kidney transplantation.
- You have problems with your liver or heart (significant problem with your heart valves or have a condition known as hypertrophic cardiomyopathy)
- 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 suffer from high blood levels of calcium.
- You have diabetes (diabetes mellitus)
- You have a condition known as gout (excruciating, sudden, unexpected, burning pain, as well as swelling, redness, warmth, and stiffness in the affected joint especially small joints. This occurs usually in big toes but can appear in other parts of the body).
- You suffer or have been diagnosed to have systemic lupus erythematosus (autoimmune disease characterized by chronic inflammation of body tissues)
- You suffer from asthma or allergies
- You develop photosensitivity reactions (if you experience an increased sensitivity of the skin to the sun with symptoms of sunburn such as redness, itching, swelling, and blistering).
- You have high level of fat (cholesterol, triglycerides) in your blood.
- You have significant electrolyte/fluid imbalance in the form of low blood levels of sodium, potassium, magnesium and chloride (warning signs are dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle cramps, fatigue, hypotension, faster heart rate,

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nausea and vomiting. Your doctor will regularly monitor your blood pressure and levels of potassium in your blood during treatment).

Take special care if you develop sudden pain in the eyes with reduced sharpness of vision. This is more likely to happen in case you have had in the past allergic reactions to sulphonamide or penicillin class of medicine. If this happens discontinue treatment and approach your doctor for advice.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **IRBEL HCT** tablets. Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding currently. If you have not told your doctor about any of the above, tell them before you start taking **IRBEL HCT** tablets.

Taking other medicines

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

Some medicines and **IRBEL HCT** may interfere with each other. These include:

- Other tablets for high blood pressure
- Lithium (medicine used to treat mental illness). Preparations containing lithium should not be taken with **IRBEL HCT** without close supervision by your doctor.
- Potassium sparing medicines or diuretics (water tablets), potassium supplements or potassium containing salt substitutes or other medicines affecting the serum potassium levels.
- Other kaliuretic diuretics (thiazide derivatives), laxatives, amphotericin, penicillin (medicine used to treat infection), carbenoxolone (medicines used to treat ulcers)
- Heparin (blood thinning

medicine which is used to stop blood clotting

- NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) medicines used to relieve pain, swelling, and other symptoms of inflammation, including arthritis
- Alcoholic drinks, sleeping tablets, strong pain killing medicines such as codeine or morphine (you may have an increased feeling of dizziness on standing up, specially when getting up from a sitting position)
- Medicines for diabetes (oral medicines or insulin); corticosteroid medicines such as prednisone, cortisone or ACTH
- Colestyramine or colestipol (cholesterol-lowering medicines)
- Digoxin (digitalis glycosides) and antiarrhythmic (medicine to control heart rhythm) [(e.g. disopyramide, amiodarone, sotalol)]
- Diazoxide (used to treat severe hypoglycaemia)
- Catecholamines [ephedrine, noradrenaline or adrenaline; drugs used for treatment of low blood pressure, heart failure, asthma or allergies (noradrenaline and adrenaline are always given under medical supervision)]
- Tubocurarine (used as muscle relaxant); medicines for gout such as probenecid or sulfinpyrazone
- Calcium supplements or calcium saving medicines like Vitamin D
- Atropine, biperiden (anticholinergic medicines used to treat Parkinson's disease, to relieve stomach cramps or spasms or used to prevent travel sickness)
- Amantadine (medicine used to treat Parkinson's disease or to prevent influenza)
- Cyclophosphamide, methotrexate (anticancer medicines)

These medicines may be affected by **IRBEL HCT** tablets, or may affect how well it works. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking **IRBEL HCT** tablets.

How to use IRBEL HCT

How much to use

Your doctor or pharmacist will tell you how much and how often you should take **IRBEL HCT** tablets. The usual dose of **IRBEL HCT** is one tablet a day. **IRBEL HCT** will usually be prescribed by your doctor if previous treatment does not produce a sufficient drop in your blood pressure. Your doctor will tell you how to switch from your previous treatment to **IRBEL HCT**.

Your doctor may prescribe **IRBEL HCT** 150 mg /12.5 mg to you when your blood pressure is not adequately controlled by irbesartan 150 mg or hydrochlorothiazide alone.

If your blood pressure is not controlled by irbesartan 300 mg or by **IRBEL HCT** 150 mg /12.5 mg then your doctor will prescribe **IRBEL HCT** 300 mg /12.5 mg to you.

And if your blood pressure is still not controlled by **IRBEL HCT** 300 mg /12.5 mg then your doctor may prescribe **IRBEL HCT** 300 mg /25 mg to you.

If your blood pressure is not satisfactorily reduced, your doctor may prescribe another medicine to be taken with **IRBEL HCT**.

IRBEL HCT are for use in adults only and are not recommended for use in children and adolescents. If a child swallows some tablets, contact your doctor immediately. Always take **IRBEL HCT** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Do not suck or chew **IRBEL HCT** tablets. Swallow the tablet whole with a glass of water.

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When to use it

You should try to take your daily dose at about the same time each day. Your doctor will advise you on the best time of the day to take your tablet. It does not matter if you take **IRBEL HCT** before or after food.

How long to use it

IRBEL HCT helps to control your high blood pressure, but does not cure it. Therefore these tablets must be taken every day. Continue taking **IRBEL HCT** until your doctor tells you to stop.

If you forget to use 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 forgotten dose.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice, or go to

Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much **IRBEL HCT** tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using IRBEL HCT

Things you must do

Continue taking **IRBEL HCT** every day as directed by your doctor, even if you have no symptoms of high blood pressure. If your condition gets worse while taking **IRBEL HCT** tablets, tell your doctor immediately. If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking **IRBEL HCT** tablets.

If you become pregnant while taking this medicine, tell your doctor immediately. Keep all of your doctor's appointments so that your progress can be checked. Have your blood pressure checked when your doctor tells you to, to make sure **IRBEL HCT** tablets are working. Get up slowly when getting out of bed or standing

up. You may feel light-headed or dizzy while taking **IRBEL HCT** tablets. This may become worse if you stand up quickly as your blood pressure may fall. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If you feel dizzy or light-headed talk to your doctor.

If you develop problems with your vision like decrease in vision or pain in eyes, tell your doctor immediately. Make sure you drink enough water during exercise and hot weather when you are taking **IRBEL HCT** tablets, especially if you sweat a lot. If you do not drink enough water while taking these tablets, you may faint or feel light-headed or sick. This is because your body does not have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor. If you have excessive vomiting and/or diarrhoea while taking **IRBEL HCT** tablets, tell your doctor. This can also mean that you are losing too much water and your blood pressure may become too low.

Things you must not do

The different strength tablets may not have the same effect, as they are absorbed slightly differently in the body. Do not take **IRBEL HCT** to treat any other complaints unless your doctor tells you to. Do not give your medicine to anyone else, even if they have the same condition as you. Do not stop taking your medicine because you are feeling better, unless advised by your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how **IRBEL HCT** affect you. As with many other medicines used to treat high blood pressure, **IRBEL HCT** may cause dizziness or light-headedness in some people. Make sure you know how you react to **IRBEL HCT** before you drive a car, operate machinery or do anything else that could be dangerous if you are

dizzy or light-headed. If you drink alcohol, dizziness or light-headedness may be worse. The hydrochlorothiazide contained in this medicine could produce a positive analytical result in an anti-doping test.

Side Effects

Like all medicines, **IRBEL HCT** can cause side effects, although not everybody gets them. Some of these effects may be serious and may require medical attention. If any of the following happens, stop taking this medicine. Tell your doctor immediately and go to Accident and Emergency department at the nearest hospital:

- Rashes, hives, itching, chest constriction, shortness of breath or swelling of face, lips, tongue, hands/ feet, fainting, high temperature, joint pain; severe skin reactions with blisters, sores and ulceration, sunburn (such as redness, itching).

If you have any of above, you may have had a serious allergic reaction or other type of reaction to **IRBEL HCT** tablets. The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Side effects reported with combination of irbesartan and hydrochlorothiazide:

Common: Increase blood levels of creatinine, creatinine kinase and blood urea nitrogen; dizziness; unusual tiredness or weakness; feeling sick; being sick; abnormal urination.

Uncommon: Low potassium level (symptoms such as nausea, diarrhoea, muscle weakness and changes in heart rhythm) in blood; decreased sodium in serum; fainting, low blood pressure; increased heart rate; swelling; feeling of dizzy or light-headed when getting up from a lying or sitting position; loose stool; swelling of hands, ankles or feet; flushing; yellowing of the skin and/or eyes; change in sexual interest or drive.

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Frequency not known: Headache; ringing in the ears; cough; taste disturbances or loss of taste; pain in the joints and bones; muscle pain; irregular heartbeat; nausea, slow weak, or absent pulse; yellowing of skin and whites of eyes with decreased appetite, abdominal pain, nausea, vomiting, dark discoloration of urine, pale stools, fever, itchy skin; liver disease; skin and lip cancer.

Others: Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills; belly pain; upper respiratory tract infections; pain or feeling of tension or fullness in the nose or cheeks; sore throat and discomfort when swallowing; runny or blocked nose, sneezing, due to inflammation in nose; difficulty or pain in passing urine, frequent urination; nervousness; muscle spasm, pain in bones and muscles; chest pain.

Side effects reported with irbesartan alone:

Increase body temperature; chills; swelling of face and upper body; increase in blood pressure; severe increase in blood pressure; abnormal heart sounds; feeling of tightness, heaviness, dull discomfort, or crushing pain that is felt behind the breastbone and may spread to the arms, neck and jaw; severe and prolonged chest pain, fast or irregular heart beat, and may be associated with nausea, vomiting and excessive sweating; irregular heart beats; cessation of normal circulation of the blood due to failure of the heart which may be accompanied by absence of pulse or breathing; itching; skin disease; bruising; redness of face; stiffness in joints; disease with painful, swollen joints caused by uric acid crystals; pain and swelling of joints; constipation; pain in stomach; feeling sick; being sick with cramps or diarrhea; excessive gas in the stomach or bowel; swelling of the belly; pain in bones and muscles; chest pain; tingling or numbness in the hands, feet or ankles; problems with eye(s) or vision; sensation of spinning or perception that surrounding objects are moving or

spinning; feelings of deep sadness and unworthiness; sleep disturbances; sleepiness; emotional disturbances; infection and pain in ears; hearing problems; swollen runny eyes; muscle cramps; injury to bones and muscles; numbness; shaking; nose bleed; difficulty in breathing; coughing up blood; excessive sweating; anxiety, and pale skin; difficulty in breathing or shortness of breath; inflammation of wind pipe and bronchi; wheezing; problems with prostate; sudden onset of a severe headache; dizziness; numbness/weakness in the face, arm, or leg, especially on one side of the body (or) altered speech and mental ability to understand; disturbed vision in one or both eyes, and loss of balance or coordination. These symptoms may occur for a short time and are reversible or may last for longer period of time; abnormal muscle breakdown which can lead to kidney problems.

Side effects reported with hydrochlorothiazide alone:

Frequency not known: Skin and lip cancer (Non-melanoma skin cancer); unusual amount of salt in the body; confusion; decreased consciousness, hallucinations (hyponatremia); increase blood levels of uric acid, glucose, cholesterol and triglycerides; changes in the rhythm or rate of the heart beat; tiredness, headaches, being short of breath when exercising, dizziness and looking pale; signs of frequent infections such as fever, chills, sore throat or mouth ulcers or bleeding or bruising more easily than normal; disease of the blood with a reduced number of red or white blood cells or platelets; light-headedness; restlessness; sensation of spinning or perception that surrounding objects are moving or spinning; tingling or numbness in the hands, feet or ankles; yellow in vision; sudden blurring of vision; coughing, difficulty breathing, wheezing; swelling of lungs; severe abdominal pain accompanied by nausea and vomiting; loss of appetite, gastric irritation, swelling, pain, redness of salivary gland due to bacterial infection; loose stools; dark

discoloration of urine, bloody or cloudy urine or any change in your urine output; kidney disease; weakness, muscle cramp; feeling of dizzy or light-headed, palpitation (when getting up from a lying or sitting position); increase body temperature; yellowing of the skin and/or eyes; feelings of deep sadness and unworthiness; sleep disturbances; sensitivity to light.

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.

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

Others: Unusual bleeding or bruising under the skin, purple or red-brown spots visible through the skin; cramps. 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.

Reporting of side effects

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 -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of IRBEL HCT

Storage: Store below 30°C. Keep out of the reach and sight of children.

Disposal: Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe 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.

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Product description

What it looks like

IRBEL HCT are pink to red coloured, film coated, oval shaped tablets debossed with 'IH1' (**150+12.5 mg**), IH2 (**300+25 mg**) on one side and plain on other side.

IRBEL HCT 300+ 12.5 mg are yellow coloured, film coated, oval shaped tablets debossed with 'IH3' on one side and plain on other side.

Ingredients

Active ingredient:

IRBEL HCT 150+12.5 mg: Each film-coated tablet contains Irbesartan Ph. Eur. 150mg/Hydrochlorothiazide Ph.Eur. 12.5mg;

IRBEL HCT 300+12.5 mg: Each film-coated tablet contains Irbesartan Ph. Eur. 300 mg/Hydrochlorothiazide Ph.Eur. 12.5 mg;

IRBEL HCT 300+25mg: Each film coated tablet contains: Irbesartan Ph. Eur. 300 mg/ Hydrochlorothiazide Ph.Eur. 25 mg

Inactive ingredients:

IRBEL HCT also contains:

Lactose monohydrate,
Microcrystalline
Cellulose (PH 101), Croscarmellose
Sodium, Hypromellose, Colloidal
anhydrous silica, Microcrystalline
Cellulose (PH 102), Magnesium
Stearate, Opadry Pink 03G54386 for
150+12.5 mg & 300 + 25 mg, Opadry
Yellow 03G52390 for 300 + 12.5 mg,
Purified Water

Coating composition of Opadry Pink 03G54386: *Hypromellose, Titanium Dioxide, Macrogol 400, Talc, Macrogol 4000, Iron oxide Red and Black;*

Coating composition of Opadry yellow 03G52390: *Hypromellose, Titanium Dioxide, Macrogol 400, Talc, Macrogol 4000, Iron oxide yellow*

MAL Number:

IRBEL HCT TABLET 150+12.5mg:
MAL12115057AZ

IRBEL HCT TABLET 300+12.5mg:
MAL12115058AZ

IRBEL HCT TABLET 300+25mg:
MAL15085026AZ

Manufacturer

SUN PHARMACEUTICAL
INDUSTRIES LIMITED
Paonta Sahib, Dist Sirmour
Himachal Pradesh-173025, INDIA

Product Registration Holder

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MALAYSIA

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