

IRBEL TABLETS

Irbesartan Tablets (150 and 300 mg)

Consumer Medication Information Leaflet (RiMUP)

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What IRBEL TABLETS is used for

IRBEL TABLETS contain a medicine called irbesartan. Irbesartan belongs to a group of medicines known as angiotensin-II receptor blocker. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels causing narrowing of blood vessels. This results in an increase in blood pressure.

IRBEL TABLETS are used in adult patients:

- to treat high blood pressure
- to protect the kidney in patients with high blood pressure, type 2 diabetes and laboratory evidence of impaired kidney function (Nephropathy in type 2 diabetic patients).

How IRBEL TABLETS works

IRBEL TABLETS prevent the binding of angiotensin-II to angiotensin-II receptors, causing the blood vessels to relax and the blood pressure to lower. Irbesartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Your doctor may give you other medicines as well as Irbel Tablets to help treat your condition.

Before you use IRBEL TABLETS

When you must not take it

Do not take **IRBEL TABLETS** if:

- you are allergic to irbesartan or any of the other ingredients of this medicine. An allergic reaction may include rash, itching, swelling of face, lips, or hands/feet, or breathing difficulties.
- you are more than 3 months pregnant. (It is also better to avoid Irbesartan in early pregnancy-see pregnancy section)
- you are breast feeding.

If you are not sure whether you should start taking this medicine talk to your doctor.

Before you start to take it

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

- if you suffer from excessive vomiting or diarrhea or dehydration
- if you are on diuretic (water tablet) therapy or on restricted dietary salt intake.
- if you suffer from high blood pressure due to narrowing of kidney blood vessels (renal artery stenosis) [renovascular hypertension], use of irbesartan may cause severe decrease in your blood pressure and kidney problems.
- if you suffer from kidney disease: In this case your doctor may perform regular blood tests, especially for measuring blood potassium levels and creatinine levels in case of poor kidney function.
- If you have had a kidney transplant
- if you have narrowing of heart valves (aortic, mitral valve stenosis) or disease of the muscle of the heart in which a portion of the muscle is thickened (obstructive hypertrophic cardiomyopathy).
- if you are suffering from a syndrome associated with increased secretion of a hormone called aldosterone by the adrenal gland characterised by high blood pressure, headache, and muscle weakness (primary aldosteronism): Irbesartan may not decrease blood pressure.

- if you have high blood pressure and high blood sugar level, therapeutic effects of Irbesartan may vary.

- if you are suffering from severe heart problems or kidney disease, treatment with Irbesartan may cause acute fall in blood pressure, increase in blood urea and creatinine, kidney failure and decrease in production of urine

- if you have high levels of potassium in your blood

If you have not told your doctor about any of the above, tell them before you start taking Irbel Tablets.

Pregnancy and Lactation

Pregnancy

Tell your doctor if you are pregnant or plan to become pregnant.

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

Your doctor will normally advise you to stop taking **IRBEL TABLETS** before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Irbel Tablets. Irbel Tablets 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.

Lactation

Do not take this medicine if you are breastfeeding.

Important information about some of the ingredients:

This medicine contains lactose, which is a type of sugar. If you have been told by your doctor that, you cannot tolerate or digest some sugars (have intolerance to some sugars), then talk to your doctor before taking this medicine.

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.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other antihypertensive (blood pressure lowering medicines) medicines and diuretics (water tablets) : These drugs may increase the blood pressure lowering effects of irbesartan
- Potassium supplements and potassium-sparing diuretics: use at the same time may increase blood potassium levels.
- Lithium: increase in blood lithium levels and toxicity may occur if lithium is administered at the same time as Irbesartan.
- Non steroidal anti inflammatory drugs (medicines used to treat pain and fever): decrease in blood pressure lowering effect may occur; may lead to an increased risk of worsening of kidney function, including possible kidney failure, and an increase in blood potassium. Caution should be exercised if you are elderly.

How to use Irbel Tablets

How much to use

Follow all directions given to you by your doctor or pharmacist carefully.

Hypertension

The recommended initial and maintenance dose is 150 mg once (1 tablet of 150 mg) a day. Your doctor may increase your dose to 300 mg (1 tablet of 300 mg or 2 tablets of 150 mg) once daily depending on blood pressure response.

Sometime your doctor may also prescribe you water tablets (low dose diuretic) along with Irbesartan, if your blood pressure is not controlled by Irbesartan alone.

Nephropathy in type 2 diabetic patients
In patients with high blood pressure and type 2 diabetes, recommended starting dose of **IRBEL TABLETS** is 150 mg (1 tablet of 150 mg) once a day. Then your doctor will increase your dose to 300 mg (1 tablet of 300 mg or 2 tablets of 150 mg) once daily as the preferred maintenance dose for the treatment of associated kidney disease.

The doctor may advise a lower dose (75 mg), especially when starting treatment in certain patients such as those on haemodialysis or you are vigorously treated with water tablets.

How to take

Swallow tablets with a glass of water. **IRBEL TABLETS** can be taken with or without food.

When to use it

You should take your tablets at the same time.

Use in children

Irbesartan tablets are not recommended in children.

How long to use it

IRBEL TABLETS helps to control your high blood pressure, but it does not cure it. Therefore **IRBEL TABLETS** must be taken every day.

Continue taking **IRBEL TABLETS** until your doctor tells you to stop.

If you forget to use it

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you use too much (overdose)

If you think you or anyone else may have taken too much **IRBEL TABLETS**, immediately telephone your doctor or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor or pharmacist.

You may need urgent medical attention. The most likely manifestations expected to occur in case of an overdose are low blood pressure and increased rate of heart beat. Decreased heart beat rate could also occur.

While you are using **IRBEL TABLETS**

Things you must do

- If you become pregnant while taking **IRBEL TABLETS** tell your doctor immediately.

- Have your blood pressure checked when your doctor tells you to, to make sure **IRBEL TABLETS** is working.

- If you are about to start on any new medicine, tell your doctor and pharmacist that you are taking **IRBEL TABLETS**

- Get up slowly when getting out of bed or standing up. You may feel light-headed or dizzy while taking **IRBEL TABLETS**, especially if you are also taking a diuretic (fluid tablet). 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. This problem is not common. If it occurs talk to your doctor.

- If you have excessive vomiting and/or diarrhoea while taking **IRBEL 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

Do not give **IRBEL TABLETS** to anyone else even if they have the same condition as you.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how **IRBEL TABLETS** affects you.

IRBEL TABLETS are unlikely to affect your ability to drive and use machines.

However, occasionally dizziness or weariness may occur during treatment of high blood pressure. If you experience these, you should consult your doctor before attempting such activities.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well

while you are taking **IRBEL TABLETS**.

IRBEL TABLETS can cause side effects, although not everybody gets them.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

If any of the following happens, stop taking **IRBEL TABLETS** tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- Cases of allergic skin reactions (rash, hives), as well as localized swelling of the face, lips and/or tongue have been reported in patients taking Irbel Tablets (frequency not known). If you think you are developing such a reaction or get shortness of breath, stop taking Irbesartan and seek immediate medical attention.

The above list includes very serious side effects. You may need urgent medical attention or hospitalization.

Tell your doctor immediately if you notice any of the following:

- yellowing of skin and whites of eyes with decreased appetite, abdominal pain (these may be manifestations of a liver problem)
- high potassium levels in the blood. Symptoms include feeling sick (nausea), diarrhoea, muscle weakness and change in heart rhythm
- inflammation of small blood vessels mainly affecting the skin (leukocytoclastic vasculitis)
- chest pain which may spread to the neck and shoulders (heart attack), chest pain (angina)
- abnormal heart rhythm, shortness of breath, swelling of the feet or legs due to fluid build-up (heart failure), severe increase in blood pressure that can lead to a stroke
- kidney problems including kidney failure, symptoms of kidney problems include passing little or no urine, drowsiness, nausea, vomiting, breathlessness.

- numbness or weakness, especially on one side of the body, confusion or trouble speaking or understanding speech, trouble seeing in one or both eyes (transient ischemic attack-mini stroke)
- build up abnormal fluid in lungs characterised by difficulty in breathing, grunting, gurgling, or wheezing sounds with breathing (pulmonary congestion)

The above list includes serious side effects that may require medical attention.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- feeling sick (nausea)/being sick (vomiting), diarrhoea, fatigue
- stomach pain, constipation, wind, sore mouth, bloating
- anxiety, nervousness, depression, emotional disturbance, dizziness, drowsiness
- pain in bones and muscles, muscle cramps, muscle weakness, pain in joint stiffness, pain or swelling in or near a joint (bursitis)
- fast heart beat (tachycardia), flushing, low blood pressure and dizziness (especially when getting up from a lying or sitting position), spinning sensation (vertigo), fainting (syncope)
- high blood pressure, abnormal heart sounds (heart murmur)
- cough, sore throat (pharyngitis), runny nose
- rash, hives, bruising, redness on the face, itching
- swelling of face or hands, legs and ankles
- indigestion/heartburn
- problems with sexual performance
- chest pain
- headache
- taste disturbance, ringing in the ears, hearing problems, ear pain, vision disturbance, discharge with itching of the eyes and crusty eyelids (conjunctivitis), other eyes and ear problems
- flu-like symptoms, such as high temperature, sore throat, runny, nose, cough and chills

- painful, swollen joints caused by uric acid crystals (gout)
- sleep disturbance, numbness, pins and needles like sensation (paresthesia), and tremor
- high or low frequency of urination (abnormal urination), problems with prostate
- dry cough which later become productive (tracheobronchitis), nose block (congestion), difficulty in breathing, wheezing

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 IRBEL TABLETS

Storage

Store below 30°C

Disposal

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

Product Description

What **IRBEL TABLETS** look like

IRBEL TABLETS 150 mg

White to off white, film coated oval shaped, biconvex tablet debossed with 'I4' on one side and plain on the other.

IRBEL TABLETS 300 mg

White to off white, film coated oval shaped, biconvex tablet debossed with 'I5' on one side and plain on the other.

Ingredients

Active ingredient:

Irbesartan 150 mg and 300 mg

Inactive ingredients: Irbel Tablets contains:

Lactose, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl methylcellulose, colloidal anhydrous silica, magnesium stearate, opadry II white OY-LS-28900 (lactose, hypromellose, titanium dioxide, macrogol) and purified water.

MAL number:

IRBEL TABLETS 150 mg:

MAL12075073AZ

IRBEL TABLETS 300 mg:

MAL12075074AZ

Manufacturer

**SUN PHARMACEUTICAL IND.
LTD.**

Village Ganguwala,
Paonta Sahib- 173025 Distt. Sirmour,
Himachal Pradesh (India).

Product Registration Holder

**RANBAXY (MALAYSIA) SDN.
BHD.**

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MALAYSIA

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