

IRBIS 150 and IRBIS 300

Irbesartan 150mg and Irbesartan 300mg

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What *IRBIS* is used for

IRBIS is used in adult patients

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

How *IRBIS* works

IRBIS belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels causing them to tighten. This results in an increase in blood pressure. *IRBIS* prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower. *IRBIS* slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Before you take *IRBIS*

When you must not take it

- If you are allergic (hypersensitive) to *IRBIS* or any other ingredients of *IRBIS*.
- If you are more than 3 months pregnant. (It is also better to avoid *IRBIS* in early pregnancy - see pregnancy section)

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

Before you start to take it

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

- If you get excessive vomiting or diarrhea
- If you suffer from kidney problems
- If you suffer from heart problems
- If you receive *IRBIS* for diabetic kidney disease. In this case your doctor may perform regular blood tests, especially for measuring blood potassium levels in case of poor kidney function.
- If you are going to have an operation (surgery) or be given anesthetics

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

Use in Children

This medicinal product should not be used in children and adolescents because the safety and efficacy has not yet been fully established.

Pregnancy and Breast feeding

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 *IRBIS* before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of *IRBIS*. *IRBIS* 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

Do not take this medicine if you are breast feeding.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. *IRBIS* 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.

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) and diuretics (water tablet) : These drugs may increase the blood pressure lowering effects of *IRBIS*.
- 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 *IRBIS*.
- 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 take *IRBIS*

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

How much to take

The usual dose is 150 mg once a day. The dose may later be increased to 300 mg once daily depending on blood pressure response.

When to take it

You can take *IRBIS* with or without food. Try to take your daily dose at about the same time each day.

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How long to take it

It is important that you continue to take *IRBIS* until your doctor tells you otherwise.

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 forgotten dose.

If you take too much (overdose)

If you think you or anyone else may have taken too much *IRBIS*, 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 taking it

Things you must do

- If you become pregnant while taking *IRBIS* tell your doctor immediately.
- Have your blood pressure checked when your doctor tells you to, to make sure *IRBIS* is working.
- If you are about to start on any new medicine, tell your doctor and pharmacist that you are taking *IRBIS*.
- Get up slowly when getting out of bed or standing up. You may feel light-headed or dizzy while taking *IRBIS*, especially if you are also taking a diuretic (water 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 diarrhea while taking *IRBIS*, 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 *IRBIS* 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 *IRBIS* affects you.

IRBIS 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

Like all medicines, *IRBIS* can cause side effects, although not everybody gets them.

Some of these effects may be serious and may require medical attention. As with similar medicines, rare cases of allergic skin reactions (rash, urticaria), as well as swelling of the face, lips and/or tongue have been reported in patients taking *IRBIS*. If you get any of these symptoms or get short of breath, stop taking *IRBIS* and contact your doctor immediately.

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

very common ($\geq 1/10$)

common ($\geq 1/100, < 1/10$)

Nervous system disorders:

Common: dizziness, orthostatic dizziness (dizziness when getting up from a lying or sitting position).

Vascular disorders:

Common: orthostatic hypotension (low blood pressure when getting up from lying or sitting position)

Gastrointestinal disorders:

Common: nausea/vomiting

Musculoskeletal and connective tissue disorders:

Common: musculoskeletal pain

General disorders and administration site condition:

Common: fatigue

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI).

Storage and Disposal of *IRBIS*

Storage

Keep out of the reach and sight of children

Store below 30°C.

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.

IRBIS 150 and IRBIS 300

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Product description

What it looks like

IRBIS 150

White to off white colored, capsule shaped, biconvex, film coated tablets debossed with '159' on one side and H on the other side.

IRBIS 300

White to off white coloured, capsule shaped, biconvex, film coated tablets debossed with '160' on one side and H on the other side

Ingredients

Active ingredient:

Irbesartan

Inactive ingredients:

Cellulose Microcrystalline, Carmellose calcium, Povidone k - 30, Aerosil 200, Calcium stearate, opadry white, purified water.

MAL number:

Manufacturer

Hetero Labs Limited

Unit V, Sy. No 439,440,441 & 458

TSHIC Formulation SEZ,

Polepally village, Jedcharla Mandal,

Mahaboobnagar Dist

Telangana, India.

Product Registration Holder

Unimed Sdn Bhd

No 53, Jalan Tembaga SD 5/2B, Bandar

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