

IRBISAT 150MG TABLET

IRBISAT 300MG TABLET

Irbesartan (150mg & 300mg)

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What Irbisat is used for

- 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 Irbisat works

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

Before you take Irbisat

-When you must not take it

- If you are allergic (hypersensitive) to irbesartan or any other ingredients of Irbisat
- If you are more than 3 months pregnant. (It is also better to avoid Irbisat in early pregnancy. Irbisat should not be given to children and adolescents (under 18 years).

-Before you start to take it

Please tell your doctor or pharmacist:

- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

-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. Irbisat does not usually interact with other medicines.

You may need to have blood checks if you take:

- potassium supplements
- salt substitutes containing potassium
- potassium-sparing medicines (such as certain diuretics)
- medicines containing lithium
- repaglinide (medication used for lowering blood sugar levels)

Your doctor may need to change your dose and/or to take other precautions: If you are taking an ACE-inhibitor or aliskiren

If you take certain painkillers, called non-steroidal anti-inflammatory drugs, the effect of irbesartan may be reduced.

Taking Irbisat with food and drink

Irbisat can be taken with or without food.

How to take Irbisat

-How much to take

Irbisat is for oral use. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water).

• Patients with high blood pressure

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.

• Patients with high blood pressure and type 2 diabetes with kidney disease.

In patients with high blood pressure and type 2 diabetes, 300 mg once daily is the preferred maintenance dose for the treatment of associated kidney disease.

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those on haemodialysis, or those over the age of 75 years. If a lower starting dose is considered necessary, the 150 mg tablet not being breakable, alternative therapy should be considered.

The maximal blood pressure lowering effect should be reached 4-6 weeks after beginning treatment.

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

-When to take it

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

-How long to take it

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

-If you forget to take it

Take the missed dose as soon as possible as you remember it. However if it is almost time for the next dose, skip the missed dose and continue your regular doing schedule. Do not take a double dose to make up for a missed one.

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-If you take too much (overdose)

If you accidentally take too many tablets, contact your doctor immediately.

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

While you are using Irbisat

-Things you must do

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Irbisat before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Irbisat. Irbisat 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. Irbisat 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

-Things you must not do

Do not stop taking without consulting doctor first. Do not give your medicine to other people who experience the same symptoms as you.

-Things to be careful of

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

- if you get excessive vomiting or diarrhoea
- if you suffer from kidney problems
- if you suffer from heart problems
- if you receive Irbisat 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 develop low blood sugar levels; particularly if you are being treated for diabetes
- if you are going to have an operation (surgery) or be given anaesthetics
- if you are taking any of the following medicines used to treat high blood pressure: - an ACE-inhibitor (for example enalapril, lisinopril, ramipril) in particular if you have diabetes-related kidney problems- aliskiren

Driving and using machines

Irbisat 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, Irbisat 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 localized swelling of the face, lips and/or tongue have been reported in patients taking irbesartan.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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 Irbisat

-Storage

Store below 30°C. KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

-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.

Products Description

-What it looks Like

Irbisat 150 mg:

White to off-white, oval shaped, film coated tablets, plain on one side and "12" on the other side.

Packaging Information:

Pack in blister pack of 28 Tablet per box

Irbisat 300 mg:

White to off-white, oval shaped, film coated tablets, plain on one side and "13" on the other side.

Packaging Information:

Pack in blister pack of 28 Tablet per box

-Ingredients:

Active Ingredient:

Each film coated tablet contains:
Irbesartan

In active Ingredients:

Mannitol, crospovidone, colloidal silicon dioxide, sodium laurylsulfate, povidone, magnesium stearate, opadry white and purified water.

-MAL number:

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Irbesartan (150mg & 300mg)

Manufacturer and Product

Registration Holder

SM Pharmaceuticals Sdn.Bhd.

(218628-M)

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Kedah Darul Aman,Malaysia

Date of Revision: 14.10.2022

Serial number:

NPRA (R2) 22/010