

BEZARTAN TABLET®

Irbesartan (150 mg, 300 mg)

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What Bezartan Tablet is used for

Bezartan Tablet is used

- 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 Bezartan Tablet works

Irbesartan 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. Irbesartan prevents the binding of angiotensin-II to these 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.

Before you use Bezartan Tablet

-When you must not use it

- If you are allergic to irbesartan or any other ingredients of this medicine.
- If you are more than 3 months pregnant. (it is also better to avoid

Bezartan in early pregnancy- see pregnancy section)

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

- Before you start to use it

Bezartan 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.

- 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.

Bezartan Tablet 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

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

Talk to your doctor or pharmacist 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

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

If you are taking Bezartan Tablet and one of the above medicines or types of

medicines, make sure your prescriber knows about it.

How to use Bezartan Tablet

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

- How much to use

Bezartan Tablet 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.

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

- When to use it

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

- How long to use it

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

- *If you take more than you should (overdose)*

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

- *If you forget to take Bezartan Tablet*

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 have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using it

- *Things you must do*

Talk to your pharmacist or doctor if your symptoms do not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

- *Things you must not do*

Do not take Bezartan Tablet to treat any other complaints unless your pharmacist or doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

- *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 are going to have an operation (surgery) or given anaesthetics.
- if you receive Bezartan Tablet 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

Use in pregnancy

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

Bezartan Tablet 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.

Use in breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Bezartan Tablet 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.

Driving and using machines

Bezartan Tablet 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, this medicine 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 localised swelling of the face, lips and/or tongue have been reported in patients taking irbesartan. If you get any of these symptoms or get short of breath, stop taking Bezartan and contact your doctor immediately.

Side effects:

• Very common: if you suffer from high blood pressure and type 2 diabetes with kidney disease, blood tests may show an increased level of potassium.

• Common: dizziness, feeling sick/vomiting, fatigue and blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatin kinase enzyme). In patients with high blood pressure and type 2 diabetes with kidney disease, dizziness when getting up from a lying or sitting position, low blood pressure when getting up from a lying or sitting position, pain in joints or muscles and decreased levels of a protein in the red blood cells (haemoglobin) were also reported.

• Uncommon: heart rate increased, flushing, cough, diarrhoea, indigestion/heartburn, sexual dysfunction (problems with sexual performance), chest pain.

Other undesirable effects where the frequency is not known are: feeling of spinning, headache, taste disturbance, ringing in the ears, muscle cramps, pain in joints and muscles, reduced number of platelets, abnormal liver function, increased blood potassium levels, impaired kidney function, inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis), and severe allergic reactions (anaphylactic shock). Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my [Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Bezartan Tablet

- *Storage*

Store below 30°C and keep out of reach of children.

Store in the original package in order to protect from light and moisture.

- 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.

Product Description

- What it looks like

Bezartan Tablet 150mg - White to off white, biconvex, oval-shaped, with marking '150' on one side and film coated tablet.

Bezartan Tablet 300mg - White, oval shape, with scored on one side, and film coated tablet

- Ingredients

Active ingredient:

Each Tablet of Bezartan tablet 150 mg and 300 mg contains irbesartan 150 mg and 300 mg.

Inactive ingredients:

- a) Bezartan Tablet 150mg
 - i. HPMC
 - ii. Lactose Monohydrate
 - iii. Microcrystalline Cellulose
 - iv. Croscarmellose Sodium
 - v. Silicon Dioxide
 - vi. Magnesium Stearate
 - vii. Opadry II White

- b) Bezartan Tablet 300mg
 - i. HPMC
 - ii. Lactose Monohydrate
 - iii. Microcrystalline Cellulose
 - iv. Croscarmellose Sodium
 - v. Silicon Dioxide
 - vi. Magnesium Stearate
 - vii. Opadry II White

- MAL number:

Bezartan Tablet 150mg:
MAL XXXXXXXXX

Bezartan Tablet 300mg:
MAL XXXXXXXXX

Manufacturer

Duopharma Manufacturing (Bangi) Sdn. Bhd.
Lot No. 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650, Bandar Baru Bangi, Selangor, Malaysia.

Product Registration Holder

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