

IRBEVELL 300mg Film-Coated Tablet Irbesartan (300mg)

IRBEVELL 150mg Film-Coated Tablet Irbesartan (150mg)

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What Irbevell is used for

Irbevell is used to treat high blood pressure and to protect the kidney in patients with high blood pressure, type 2 diabetes and impaired kidney function.

How Irbevell works

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

Before you use Irbevell

- When you must not use it

Do not take Irbevell if:

- You are allergic to Irbesartan or any ingredients of Irbevell
- You are pregnant more than 3 months
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren (anti-hypertensive medicine)

Pregnancy and lactation

It is not recommended to take

Irbevell during the first trimester and do not take Irbevell during the second and third trimester.

Do not take Irbevell if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Talk to your doctor before taking irbesartan and 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 irbesartan 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 anaesthetics
- if you are taking any of the following medicines used to treat high blood pressure i.e. ACE inhibitor (for example enalapril, lisinopril, ramipiril), in particular if you have diabetes-related kidney problems and taking aliskiren

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

Children and adolescents:

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

- Taking other medicines

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

Your doctor may need to change your dose and/or to take other precautions if you are taking an Aliskiren-containing

products or ACE-inhibitor.

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. Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking this medicine.

How to use Irbevell

Irbesartan is not recommended for use in children and adolescents

- How much to use

Irbevell is for oral use. Swallow the tablet with sufficient amount of fluid.

Patient with high blood pressure

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

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

- 300 mg once daily is preferred dose for the treatment of associated kidney disease.
- The doctor may advise a lower dose if you undergo haemodialysis or if you over the age of 75 years.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

You can take Irbevell before or after meal. Try to take daily dose at about the same time each day.

- How long to use it

Continue taking Irbevell for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If overdosage occurs, in all cases treatment should be discontinued and you should immediately go to your nearest hospital's Emergency Department.

Overdose of Irbevell could cause low blood pressure, increased heartbeat, low potassium in your blood, muscle cramp and dizziness.

You should monitor the symptoms closely and activated charcoal may be used to treat overdose symptoms.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Irbevell.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Irbevell to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

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

Irbesartan 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.

Side effects

Like all medicines, Irbevell can cause side effects, although not everybody gets them. Possible side effects include:

- Hyperkalaemia
- Increase heartbeat
- Postural hypotension – feeling dizzy or faint during standing
- Flushing
- Headache and dizziness
- Cough
- Nausea
- Vomiting
- Diarrhoea
- Heartburn
- Impaired renal function
- Urticaria – itchy rashes
- Joint pain
- Inflammation of liver
- Jaundice
- Thrombocytopenia- deficiency in platelet; agent to clot the blood
- Sexual dysfunction
- Tinnitus – ringing or buzzing in the ears

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 Irbevell

- 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.

Product Description

- What it looks like

- **Irbevell 300 mg FCT:**
White color, round film-coated tablet, convex, plain on both sides, diameter: 11.8 – 12.2 mm, thickness: 5.8 – 6.8 mm

- **Irbevell 150 mg FCT:**
White color, round film-coated tablet, convex, plain on both sides, diameter: 9.8 – 10.3 mm, thickness: 4.1 – 5.1 mm

- Ingredients

- Active ingredient(s):
Irbesartan

- Inactive ingredients:
Lactose Monohydrate, Hypromellose, Croscarmellose Sodium, Colloidal Silicon Dioxide, Microcrystalline Cellulose, Titanium Dioxide, Magnesium Stearate, Macrogol 6000, Purified water

- Packaging

Box of:

- 2 blisters X 10 film-coated tablets
- 3 blisters X 10 film-coated tablets
- 10 blisters X 10 film-coated tablets

- MAL number

Irbevell 300 mg FCT:
MAL18016061AZ

Irbevell 150 mg FCT:
MAL23046016AZ

Manufacturer

PT. Novell Pharmaceutical
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Product Registration Holder Averroes
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