

APO-Irbesartan

Irbesartan

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about irbesartan. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

What this medicine is used for

Irbesartan is used to treat high blood pressure and kidney disease in type 2 diabetic patients with high blood pressure. It belongs to a group of medicines known as angiotensin-II receptor antagonists.

How it works

Irbesartan relaxes your blood vessels, helping to lower your blood pressure. It also slows the decrease of kidney function in type 2 diabetic patients with high blood pressure.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- irbesartan
- any other angiotensin-II receptor antagonists or 'sartans'
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you have or have had the following medical conditions:

- diabetes or moderate to severe kidney impairment, and you are taking aliskiren
- diabetic nephropathy and are on an ACE Inhibitor

Do not take this medicine if you are pregnant.

Irbesartan may affect your developing baby if you take it during pregnancy.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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 allergies to any other medicines, foods, preservatives or dyes.

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

- kidney problems, kidney transplant or dialysis
- heart problems
- liver problems
- diabetes
- high levels of potassium in your blood
- recent excessive vomiting or diarrhoea
- you are strictly restricting your salt intake
- psoriasis

Tell your doctor if you are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are planning to have surgery, dental treatment or an anaesthetic.

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

Taking other medicines

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

Some medicines may interact with irbesartan. These include:

- other tablets for high blood pressure
- fluid tablets or diuretics
- lithium or lithium containing medicines (for example Lithicarb)
- potassium tablets, potassium containing salt substitutes or other medicines that may increase potassium
- anti-inflammatory medicines ((these are used to relieve pain, swelling and other symptoms of inflammation, including arthritis) and include nonsteroidal anti-inflammatory agents - NSAIDs (for example Voltaren, Indocid, ibuprofen) and COX-2 inhibitors)

Taking a combination of irbesartan with a thiazide diuretic (fluid tablet) and an anti-inflammatory medicine may damage your kidneys. It may also reduce the effect Irbesartan has in reducing blood pressure

- a medicine containing aliskiren. Taking Irbesartan with aliskiren may affect your blood pressure, electrolyte balance and your kidney function
- medicines to treat diabetes, such as repaglinide. Irbesartan might induce hypoglycaemia; low blood sugar

If you are taking any of these, you may need a different dose, or you may need to take different medicines.

Other medicines not listed above may also interact with irbesartan.

How to take this medicine

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

They may differ to the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine you should take, depending on your condition and whether you are taking any other medicines.

High blood pressure:

The usual starting dose is 150 mg daily. This can be increased to 300 mg daily on doctors' advice.

Kidney disease caused by diabetes and high blood pressure:

The usual starting dose is 300 mg daily.

How to take it

Swallow the tablets whole with a glass of water.

When to take it

Take this medicine at about the same time each day.

Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

Otherwise, take it as soon as you remember and then go back to taking

your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much of this medicine.

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

You may need urgent medical attention.

While you are using this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking irbesartan.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

If you become pregnant while taking irbesartan, tell your doctor immediately.

Tell your doctor if you are about to have any blood tests.

Tell your doctor if you are going to have surgery or an anaesthetic or are going into hospital.

Make sure you drink enough water during exercise and hot weather, especially if you sweat a lot.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

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

Do not take your medicine to treat any other complaint unless your doctor tells you to.

Do not stop taking your medicine or change the dosage without first checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

Side effects

Tell your doctor and pharmacist as soon as possible if you do not feel well while you are taking irbesartan.

This medicine helps most people with high blood pressure, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

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

Tell your doctor if you notice any of the following:

- headache
- dizziness or light-headedness
- unusual tiredness, weakness, fatigue
- nausea or vomiting
- low blood glucose levels
- decreased number of red blood cells (anaemia – symptoms include tiredness, headaches, being short of breath when exercising, dizziness and looking pale)

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- skin rash or itchiness
- aching muscles or joints not caused by exercise
- muscle pain or weakness
- buzzing, ringing or other persistent noise in the ears
- yellowing of the skin and/or eyes
- passing little urine, drowsiness, nausea, vomiting, breathlessness, loss of appetite, weakness (signs of kidney disease)
- nausea, diarrhoea, muscle weakness and change in heart rhythm (signs of high potassium levels in the blood)
- symptoms that may indicate liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine

The above list includes serious side effects and you may need medical attention.

If any of the following occur, do not take any more of this medicine and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body;
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash (signs of an allergic reaction)

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Storage and Disposal

Storage

Keep your medicine in its pack until it is time to take it.

If you take your medicine out of its pack it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine left over.

Product description

What it looks like

White to off-white, oval shaped, biconvex, film-coated tablet.

75 mg tablets: Debossed with "L172" on one side and "75" on the other side. AUST R 213325.

150 mg tablets: Debossed with "L173" on one side and "150" on the other side. AUST R 213310.

300 mg tablets: Debossed with "L174" on one side and "300" on the other side. AUST R 213311.

Available in blister packs of 30 tablets.

* Not all strengths may be available.

Ingredients

Each tablet contains 75 mg, 150 mg or 300 mg of irbesartan as the active ingredient.

It also contains the following:

- lactose monohydrate
- croscarmellose sodium
- povidone
- magnesium stearate
- Opadry II complete film coating system 30F58652 white (ARPING 107860 consisting of hypromellose, macrogol 4000 and titanium dioxide).

Contains sugars as lactose.

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
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