

APO-Irbesartan

Contains the active ingredient irbesartan

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

The name of your medicine is APO-Irbesartan. It contains the active ingredient irbesartan.

It is used to treat:

- high blood pressure
- kidney disease in patients with high blood pressure and type 2 diabetes.

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.

How it works

Irbesartan belongs to a group of medicines known as angiotensin-II receptor antagonists.

Angiotensin II is a substance produced in the body which causes blood vessels to tighten. Irbesartan blocks angiotensin-II and therefore relaxes your blood vessels. This helps to lower your blood pressure.

Irbesartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- You are taking a medicine containing aliskiren and either have diabetes or moderate to severe kidney impairment.
- You have damage to your kidneys caused by diabetes, called diabetic nephropathy, and are on an ACE Inhibitor (used to treat high blood pressure).

- **You are pregnant.**

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

- **You are hypersensitive to, or have had an allergic reaction to, irbesartan or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, 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; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**

- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney problems, kidney transplant or dialysis
 - heart problems
 - liver problems
 - diabetes
 - high levels of potassium in your blood
 - recent excessive vomiting or diarrhoea
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant.
4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are strictly restricting your salt intake.
9. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available 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 (e.g. lithium carbonate)
- potassium tablets and potassium containing salt substitutes (e.g. Span-K, Slow-K, Mag-K) or other medicinal products that may increase potassium

- anti-inflammatory medicines (these are used to relieve pain, swelling and other symptoms of inflammations, including arthritis) and include non-steroidal inflammatory agents - NSAIDs (e.g. diclofenac, indomethacin) and COX-2 inhibitors (e.g. celecoxib).

Taking a combination of irbesartan with a thiazide diuretic (fluid tablet) and an anti-inflammatory medicine may damage your kidneys.

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 carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

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

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

How to take it

The tablets should be taken as directed by your doctor. The tablets should be swallowed whole with a glass of water.

When to take it

Take this medicine at 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 before, with or after food.

How long to take it for

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 to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel:13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- 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 while you are on the medication, especially if you sweat a lot.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

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

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking APO-Irbesartan or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- headache
- dizziness or light-headedness (vertigo)
- unusual tiredness or weakness, fatigue
- nausea/vomiting

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

These may be serious side effects and you may need medical attention

- skin rash or itchiness
- aching muscles or aching joints, not caused by exercise
- muscle pain
- buzzing, ringing or other persistent noise in the ears
- yellowing of the skin and/or eyes, also called jaundice
- symptoms that may indicate kidney disease, such as passing little or no urine, drowsiness, nausea, vomiting, breathlessness, loss of appetite and weakness
- symptoms that may indicate high potassium levels in the blood such as nausea, diarrhoea, muscle weakness and change in heart rhythm.

Allergic reactions

If you think you are having an allergic reaction to is APO-Irbesartan, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hayfever-like symptoms.

Storage and disposal

Storage

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

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

Keep your medicine in a cool dry place where the temperature will stay 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Irbesartan looks like

75 mg tablets: white to off-white, oval shaped, biconvex, film-coated tablet debossed with "L172" on one side and "75" on the other side.

150 mg tablets: white to off-white, oval shaped, biconvex, film-coated tablet debossed with "L173" on one side and "150" on the other side.

300 mg tablets: white to off-white, oval shaped, biconvex, film-coated tablet debossed with "L174" on one side and "300" on the other side.

APO-Irbesartan is 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 inactive ingredients:

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

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Irbesartan 75 mg tablets (blister pack): AUST R 213325.

APO-Irbesartan 150 mg tablets (blister pack): AUST R 213310.

APO-Irbesartan 300 mg tablets (blister pack): AUST R 213311.

Sponsor

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