

APO-Irbesartan HCTZ Tablets

Contains the active ingredients, irbesartan and hydrochlorothiazide

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 HCTZ. 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.

Use in Children

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

What this medicine is used for

The name of your medicine is APO-Irbesartan HCTZ. It contains the active ingredient irbesartan and hydrochlorothiazide (HCTZ).

It is used to treat high blood pressure, which doctors call hypertension.

Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) which means your blood pressure stays high, even when you are calm and relaxed.

There are usually no symptoms of high blood pressure. The only way of knowing that you have hypertension is to have your blood pressure checked on a regularly basis.

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

APO-Irbesartan HCTZ contains irbesartan and hydrochlorothiazide. Both medicines reduce blood pressure in different ways.

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.

Hydrochlorothiazide belongs to the class of medicines known as diuretics. Diuretics cause an increase in the volume of urine. They also help with lowering blood pressure particularly when combined with other blood pressure reducing medicines.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be given to a child.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are pregnant or intend to become pregnant.**

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

- **You are not producing urine.**
- **You are taking a medicine containing aliskiren and either have diabetes or moderate to severe kidney impairment.**
- **Do not take this medicine if you have damage to your kidneys caused by diabetes, called 'diabetic nephropathy', and are on an ACE Inhibitor (used to treat high blood pressure**
- 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.
- **You have had an allergic reaction to irbesartan or hydrochlorothiazide or to sulfonamide derived medicines, or any of the ingredients listed at the end of this leaflet.**

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, itching or hives on the skin.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

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
 - gout
 - lupus erythematosus
 - high or low levels of potassium or sodium or other electrolytes in your blood or you are restricting your salt intake
 - primary aldosteronism
 - sympathectomy
 - allergies or asthma.
3. You have recently had excessive vomiting or diarrhoea or think you are dehydrated.
4. You are taking diuretics
5. You are hypersensitive to, or have had an allergic reaction to, penicillin.
6. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant.
7. 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.
8. You are planning to have surgery or an anaesthetic.
9. You are currently receiving or are planning to receive dental treatment.

Taking other medicines

Before you start taking this medicine, tell your doctor if 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 HCTZ. These include:

- other medicines for high blood pressure
- other fluid tablets or diuretics

- lithium or lithium-containing medicines
- potassium tablets, potassium containing salt substitutes or other medicinal products 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 and COX-2 inhibitors. Taking a combination of Irbesartan HCTZ and an anti-inflammatory medicine may damage your kidneys
- alcohol
- sleeping tablets
- strong pain killing medicines such as codeine or morphine
- medicines for diabetes (oral tablets or capsules or insulins)
- calcium supplements, medicines containing calcium or calcium sparing drugs (for example Vitamin D therapy)
- medicines for gout
- powder or granules used to help reduce cholesterol
- heart medicines such as digoxin or antiarrhythmic medicines such as sotalol
- corticosteroid medicines such as prednisone, cortisone or ACTH
- medicines used to treat cancer (cytotoxic medicines)
- amantadine, a medicine used to treat Parkinson's disease or to prevent influenza
- anticholinergic medicines, these can be used to treat Parkinson's disease, to relieve stomach cramps or spasms or used to prevent travel sickness
- medicines used during surgery
- medicines used in an emergency situation such as adrenaline.

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 HCTZ.

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.

Usually patients start with one 150/12.5 mg tablet once a day, however some patients may need a lower starting dose. Your doctor will tell you if this is necessary. The full blood pressure lowering effect of Irbesartan HCTZ should be reached about 6-8 weeks after starting treatment.

Depending on how your blood pressure responds, your daily dose of Irbesartan HCTZ may need to be increased. Most patients take either 150/12.5mg or 300mg/12.5 each day. However the daily dose should not exceed 300/25 mg.

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

How to take it

The tablets should be swallowed whole with a drink 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.

To help you remember to take your tablets each day, APO-Irbesartan HCTZ tablets are supplied in a Calendar pack with the foil backing marked with the days of the week. This may help you to remember to take your tablets. All of the tablets in the pack are the same.

When you start a new strip of tablets, take the tablet marked "START". On

the next day, take the tablet marked with the relevant day of the week.

Continue taking your tablets each day until all of the tablets are taken. Commence the next strip at "START" and continue as before.

It does not matter if you take APO-Irbesartan HCTZ before 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 unwanted 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 become pregnant or plan to breastfeed
- you are about to have any blood tests
- you are going to have surgery or dental treatment.

Get up slowly when getting out of bed or standing up especially during the first few doses or if your dose is increased. You may feel light-headed or dizzy while taking this medicine. This may become worse if you stand up quickly as your blood pressure may fall. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this occurs, talk to your doctor.

Make sure you drink enough water during exercise and hot weather, especially if you sweat a lot. If you do not drink enough water, you may faint or feel lightheaded or sick. This is because your body does not have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor.

If you have excessive vomiting and/or diarrhoea while taking this medicine, tell your doctor. This can also mean that you are losing too much water and your blood pressure may become too low.

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 or pharmacist 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.

As with many other medicines used to treat high blood pressure, Irbesartan HCTZ may cause dizziness or light-headedness in some people.

If you drink alcohol, dizziness or light-headedness may be worse.

The hydrochlorothiazide contained in this medicine could produce a positive analytical result in an anti-doping test.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking irbesartan HCTZ 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
- unusual tiredness or
- weakness,
- fatigue
- pain in the stomach or gut; nausea and/or vomiting
- sexual problems

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

These may be serious side effects.

You may need medical attention:

- skin rash or itchiness
- aching muscles or aching joints, not caused by exercise
- muscle pain, weakness or paralysis of muscles
- buzzing, ringing or other persistent noise in the ears
- changes in heart rhythm
- you are not urinating (passing water) as much as normal
- numbness or tingling in fingers or toes
- painful, swollen joints which may be symptoms of gout
- fainting
- yellowing of the skin and/or eyes, also known as jaundice
- symptoms that may occur if you have developed diabetes, such as excessive thirst, passing greatly increased amounts of urine, increased appetite with weight loss, feeling tired, drowsy, weak, depressed, irritable and generally unwell
- 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 changes in heart rhythm
- symptoms that may indicate liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to Irbesartan HCTZ, 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, 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 they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What it looks like

APO-Irbesartan HCTZ 150/12.5 mg is a peach, oval, biconvex film-coated tablet debossed with "L183" on one side and plain on the other side.

APO-Irbesartan HCTZ 300/12.5 mg is a peach, oval, biconvex film-coated tablet debossed with "L184" on one side and plain on the other side.

APO-Irbesartan HCTZ 300/25 mg is a pinkish brown, oval, biconvex film-coated tablet debossed with "L185" on one side and plain on the other side.

Ingredients

Each APO-Irbesartan HCTZ 150/12.5 mg tablet contains 150 mg of irbesartan and 12.5 mg of hydrochlorothiazide as the active ingredients.

Each APO-Irbesartan HCTZ 300/12.5 mg tablet contains 300 mg of irbesartan and 12.5 mg of hydrochlorothiazide as the active ingredients.

Each APO-Irbesartan HCTZ 300/25 mg tablet contains 300 mg of irbesartan and 25 mg of hydrochlorothiazide as the active ingredients.

It also contains the following inactive ingredients:

- lactose
- croscarmellose sodium
- povidone
- pigment blend PB-24899 (ARPING 107861 consisting of iron oxide red, iron oxide yellow and lactose)
- magnesium stearate.
- APO-Irbesartan HCTZ 150/12.5 and APO-Irbesartan HCTZ 300/12.5 tablets also contain Opadry II complete film coating system 30F84418 pink (ARPING 107862 consisting of iron oxide yellow, iron oxide red, hypromellose, lactose, macrogol 4000 and titanium dioxide).
- APO-Irbesartan HCTZ 300/25 tablets also contain Opadry II complete film coating system 30F86974 brown (ARPING 107863 consisting of iron oxide yellow, iron oxide red, iron oxide black, hypromellose, lactose,

macrogol 4000 and titanium dioxide).

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

APO-Irbesartan HCTZ is available in blister packs of 30 tablets.

* Not all strengths may be available.

Australian Registration Numbers

APO-Irbesartan HCTZ 150/12.5 mg tablets (blister pack): AUST R 213302

APO-Irbesartan HCTZ 300/12.5 mg tablets (blister pack): AUST R 213303.

APO-Irbesartan HCTZ 300/25 mg tablets (blister pack): AUST R 213305.

Sponsor

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