

# APO-Irbesartan HCTZ Tablets

*Irbesartan and hydrochlorothiazide*

## 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 HCTZ. 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 HCTZ is used to treat high blood pressure (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 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.

#### How it works

This product contains both irbesartan and hydrochlorothiazide (HCTZ). 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.

HCTZ 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.

**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 for children.

### Before you take this medicine

#### When you must not take it

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

- irbesartan
- hydrochlorothiazide
- sulfonamide derived medicines,
- 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
- itching or hives on the skin.

**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.

**Do not take this medicine if you are not producing urine.**

**Do not take this medicine if 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 inhibitors or a group of medicines known as AIIAs (medicines also used to treat high blood pressure).**

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

#### 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:**

- psoriasis or a history of psoriasis
- 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
- have been taking diuretics. These are medicines that reduce fluid retention in your body and are often used to treat high blood pressure.
- allergies or asthma
- recent excessive vomiting or diarrhoea, dehydration
- hypersensitivity to, or have had an allergic reaction to, penicillin
- you have had skin cancer, or you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking irbesartan HCTZ.
- have a decrease in your vision or pain in one or both of your eyes. If so, you should discontinue Avapro HCT tablet treatment and seek prompt medical attention, as these could be symptoms of fluid accumulation in the eye (choroidal effusion) or an increase of pressure in your eye (glaucoma) and can happen within hours to weeks of taking Avapro HCT tablets. This can lead to permanent vision loss, if not treated. If you have had a penicillin or sulfonamide (sulfur

drug) allergy, you can be at higher risk of developing this.

**Do not take this medicine if you are taking diuretics.**

**Do not take this medicine if you are breastfeeding until you and your doctor have discussed the risks and benefits involved.**

**Do not take this medicine 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. 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:

- medicines for the heart or high blood pressure (e.g. digoxin, sotalol, other fluid tablets or diuretics)
- lithium, used for mood disorders
- potassium tablets, potassium containing salt substitutes or other medicinal products that may increase potassium levels in the blood (trimethoprim-containing medicines)
- anti-inflammatory medicines such as NSAIDs used to relieve pain. Taking a combination of irbesartan HCTZ and an anti-inflammatory medicine or with a thiazide diuretic (fluid tablet) may damage your kidneys
- alcohol
- sleeping tablets
- strong pain killing medicines such as codeine or morphine
- medicines for diabetes (oral tablets/capsules or insulins or a medicine containing aliskiren)
- medicines to treat diabetes, such as repaglinide. Avsartan HCT might induce hypoglycaemia; low blood sugar.
- calcium supplements, medicines containing calcium or calcium sparing drugs (e.g. Vitamin D therapy)
- medicines for gout
- powder or granules used to help reduce cholesterol
- corticosteroid medicines such as prednisone, cortisone or ACTH
- medicines used to treat cancer (cytotoxic medicines)
- medicines used to treat Parkinson's disease (e.g. amantadine) or anticholinergic medicines to relieve stomach cramps, spasms or used to prevent travel sickness
- carbamazepine, used for epilepsy
- medicines used during surgery
- medicines used in an emergency 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.

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## How to take this medicine

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**Follow carefully all directions given to you by your doctor.**

They may differ to the information contained in this leaflet.

### *How much to take*

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

**The usual dose is one tablet taken once a day.** Depending on how your blood pressure responds, your doctor may change your dose.

### *How to take it*

**The tablets should be swallowed 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. It 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 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 the tablets are taken. Commence the next strip at "START" and continue as before.

It does not matter if you take this medicine before or after 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 unwanted 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 the Emergency Department 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.**

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## While you are using this medicine

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### *Things you must do*

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking this medicine.**

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

**Tell your doctor immediately if you become pregnant whilst taking this medicine.**

**Tell your doctor if you are about to have any blood tests, surgery or dental treatment, especially any treatment that may need anaesthetic.**

**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.

**Tell your doctor if you experience an increased sensitivity of the skin to the sun with symptoms of sunburn (such as redness, itching, swelling, blistering) occurring more quickly than normal.**

**Go to your doctor regularly for a check-up.**

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 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 antidoping test.**

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## Side effects

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

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

**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:**

- 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
- blurred vision, eye pain
- 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
- excessive thirst, passing greatly increased amounts of urine, increased appetite with weight loss, feeling tired, drowsy, weak, depressed, irritable and generally unwell (signs of diabetes)
- passing little or no urine, drowsiness, nausea, vomiting, breathlessness, loss of appetite and weakness (signs of kidney disease)
- nausea, diarrhoea, muscle weakness and changes in heart rhythm (signs of high potassium levels in the blood)
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes (jaundice) and dark coloured urine (signs of liver disease)
- exacerbation of psoriasis
- disturbances in your vision (such as blurred vision and seeing haloes around lights) and eye pain

The above list includes serious side effects that may need medical attention:

**If any of the following occur, tell your doctor immediately or go to the Emergency department at your nearest hospital:**

- 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, hay fever-like symptoms (signs of an allergic reaction)

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

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

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## Storage and Disposal

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### *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 windowsill 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.**

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## Product description

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### *What it looks like*

#### **150/12.5 mg tablets**

Peach, oval, biconvex film-coated tablet debossed with "L183" on one side and plain on the other side.

AUST R 213302.

#### **300/12.5 mg tablets**

Peach, oval, biconvex film-coated tablet debossed with "L184" on one side and plain on the other side.

AUST R 213303.

#### **300/25 mg tablets**

Pinkish brown, oval, biconvex film-coated tablet debossed with "L185" on one side and plain on the other side.

AUST R 213305.

Available in blister packs of 30 tablets.

\* Not all strengths may be available.

### *Ingredients*

Each tablet contains either 150 mg or 300 mg of irbesartan and 12.5 mg or 25 mg of hydrochlorothiazide as the active ingredients.

It also contains the following inactive ingredients:

- lactose monohydrate
- croscarmellose sodium
- povidone
- pigment blend PB-24899 (ARPING 107861 consisting of iron oxide red, iron oxide yellow and lactose)
- magnesium stearate
- 150/12.5 and 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)
- 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 does not contain gluten, tartrazine or any other azo dyes.

### *Sponsor*

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