

Irbesartan HCTZ AMNEAL

contains the active ingredients irbesartan and hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about IRBESARTAN HCTZ AMNEAL.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking IRBESARTAN HCTZ AMNEAL against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What is IRBESARTAN HCTZ AMNEAL

IRBESARTAN HCTZ AMNEAL tablets contain two medicines, irbesartan and hydrochlorothiazide.

Both these medicines are in the tablets your doctor has prescribed for you.

What IRBESARTAN HCTZ AMNEAL is used for

IRBESARTAN HCTZ AMNEAL lowers high blood pressure, which doctors call hypertension.

Your doctor measured your blood pressure and found it to be too high.

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 regular basis. High blood pressure, if not treated, can damage blood vessels in several organs such as the heart, the kidneys, the brain and the eyes. This may lead to heart attacks, heart or kidney failure, strokes, or blindness. There are usually no symptoms of high blood pressure before damage occurs, so your doctor needs to measure your blood pressure to see if it is too high.

High blood pressure can be treated and controlled with medicines such as IRBESARTAN HCTZ AMNEAL. Your doctor may also have recommended that you adjust your lifestyle to help to lower your high blood pressure (losing weight, avoiding smoking, reducing alcohol consumption and restricting the amount of salt in the diet). Your doctor may also have encouraged the practice of regular, mild (not strenuous) exercise such as walking, swimming, etc.

What IRBESARTAN HCTZ AMNEAL does and how it works

IRBESARTAN HCTZ AMNEAL 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.

Your doctor may have prescribed IRBESARTAN HCTZ AMNEAL for another use. If you want more information, ask your doctor.

When you must not take IRBESARTAN HCTZ AMNEAL

Do not take IRBESARTAN HCTZ AMNEAL if:

- you are pregnant (or think you may be pregnant) or are planning to become pregnant
Your baby may absorb this medicine in the womb and there is a possibility of harm to the baby.
- you are breast-feeding.
- you are allergic to irbesartan or hydrochlorothiazide or to sulfonamide derived medicines, or to any of the ingredients listed under Product Description at the end of this leaflet.

- you are taking a medicine containing aliskiren and either have diabetes or moderate to severe kidney impairment
- you are not producing urine.
- the packaging is torn or shows signs of tampering.
- the expiry date on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure if you should start taking IRBESARTAN HCTZ AMNEAL, talk to your doctor.

IRBESARTAN HCTZ AMNEAL should not be given to children.

Before you start to take it

Tell your doctor if:

- you are or intend to become pregnant or plan to breast-feed IRBESARTAN HCTZ AMNEAL should not be used during pregnancy or while breast-feeding
- you have recently had excessive vomiting or diarrhoea or think you are dehydrated
- you suffer from any medical conditions especially:
 - kidney problems, or have had a kidney transplant or dialysis
 - heart problems
 - liver problems, or have had liver problems in the past
 - diabetes
 - gout or have had gout in the past
 - lupus erythematosus
 - high or low levels of potassium or sodium or other electrolytes in your blood
 - primary aldosteronism
- you are strictly restricting your salt intake
- you are lactose intolerant or have had any allergies to any other medicine or any other substances, such as foods, preservatives or dyes.
- have had a sympathectomy
- you have been taking diuretics

- you have a history of allergy or asthma.

Be sure you tell your doctor about any of these things before you take any IRBESARTAN HCTZ AMNEAL.

Taking IRBESARTAN HCTZ AMNEAL with 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.

It is especially important that you tell your doctor if you are taking or plan to take any of the following:

- other tablets for high blood pressure
- other water tablets or diuretics
- lithium or lithium-containing medicines (e.g. Lithicarb)
- potassium tablets (e.g. Span-K, Slow-K, Mag-K)
- potassium containing salt substitutes (e.g. Pressor-K)
- 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 (for example Celebrex). Taking a combination of Irbesartan HCTZ AMNEAL and an anti-inflammatory medicine, alone or with a thiazide diuretic (fluid tablet) may damage your kidneys. It may also reduce the effect IRBESARTAN HCTZ AMNEAL has on reducing blood pressure.
- a medicine containing aliskiren. Taking Irbesartan HCTZ AMNEAL with aliskiren may affect your blood pressure, electrolyte balance and your kidney function
- alcoholic drinks
- sleeping tablets

- strong pain killing medicines such as codeine or morphine
- medicines for diabetes (oral tablets or capsules or insulin)
- 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 (Questran Lite or Colestid Granules)
- heart medicines such as digoxin or antiarrhythmic medicines (e.g. Sotacor®)
- corticosteroid medicines such as prednisone, cortisone or ACTH
- medicines used to treat cancer (cytotoxic medicines)
- amantadine (symmetrel), a medicine used to 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
- carbamazepine anticonvulsant medication (such as Tegretol)
- medicines used during surgery
- medicines used in an emergency situation such as adrenaline.

Your doctor will decide whether your treatment needs to be altered or whether you should have check ups more frequently.

How to take IRPRESTAN HCTZ

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

How much to take

IRBESARTAN HCTZ AMNEAL will usually be prescribed by your doctor if previous treatment does not produce a sufficient drop in your blood pressure. Your doctor will tell you how to switch from your

previous treatment to IRPRESTAN HCTZ.

The usual starting dose is one tablet once a day. The full blood pressure lowering effect should be reached 6-8 weeks after beginning treatment. If your blood pressure is not satisfactorily reduced with IRPRESTAN HCTZ, your doctor may prescribe another medicine to be taken with IRPRESTAN HCTZ.

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 box, ask your doctor or pharmacist for help.

How to take IRPRESTAN HCTZ

You should always take your daily dose of IRBESARTAN HCTZ AMNEAL at about the same time each day. Taking your IRBESARTAN HCTZ AMNEAL tablets at the same time each day will have the best effect.

It does not matter whether you take IRBESARTAN HCTZ AMNEAL tablets before or after food.

How long to take it:

IRBESARTAN HCTZ AMNEAL helps to control your high blood pressure, but does not cure it. Therefore IRBESARTAN HCTZ AMNEAL must be taken every day. Continue taking IRBESARTAN HCTZ AMNEAL until your doctor tells you to stop.

If you miss a dose:

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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

If you take too much IRBESARTAN HCTZ AMNEAL (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much IRPRESTAN HCTZ. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much IRPRESTAN HCTZ, you may feel dizzy or lightheaded.

While you are taking IRPRESTAN HCTZ

Things you must do:

- If you become pregnant while taking IRBESARTAN HCTZ AMNEAL tell your doctor immediately.
- Have your blood pressure checked when your doctor tells you to, to make sure IRBESARTAN HCTZ AMNEAL is working.
- If you are about to start on any new medicine, tell your doctor and pharmacist that you are taking IRBESARTAN HCTZ AMNEAL.
- Get up slowly when getting out of bed or standing up. You may feel light-headed or dizzy while taking IRBESARTAN HCTZ AMNEAL. 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 you get dizzy or lightheaded talk to your doctor.

- If you plan to have surgery or other treatment (even at the dentist) that needs an anaesthetic, make sure that you tell your doctor or dentist that you are taking IRBESARTAN HCTZ AMNEAL
- Make sure you drink enough water during exercise and hot weather when you are taking IRBESARTAN HCTZ AMNEAL, especially if you sweat a lot.
If you do not drink enough water while taking IRBESARTAN HCTZ AMNEAL, you may faint or feel light-headed 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 IRBESARTAN HCTZ AMNEAL, tell your doctor. This can also mean that you are losing too much water and your blood pressure may become too low.

Things you must not do:

- Do not give IRBESARTAN HCTZ AMNEAL tablets to anyone else, even if they have the same condition as you.

Things to be careful of:

- Be careful driving or operating machinery until you know how IRBESARTAN HCTZ AMNEAL affects you. As with many other medicines used to treat high blood pressure, IRBESARTAN HCTZ AMNEAL may cause dizziness or light-headedness in some

people. Make sure you know how you react to IRBESARTAN HCTZ AMNEAL before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed.

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.

Side effects

IRBESARTAN HCTZ AMNEAL 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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking IRBESARTAN HCTZ AMNEAL.

Tell your doctor if you notice any of the following and they worry you:

- headache
- dizziness or light-headedness (vertigo)
- unusual tiredness or weakness, fatigue
- pain in the stomach, nausea/vomiting
- sexual problems.

These are generally mild and do not normally require treatment to be interrupted.

Tell your doctor immediately if you notice any of the following:

- skin rash or itchiness
- aching muscles or aching joints, not caused by exercise
- muscle pain or 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 called 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 change in heart rhythm
- disturbances in your vision (such as blurred vision and seeing haloes around lights) and eye pain

These are serious side effects. Skin rash and itchiness may be symptoms of an allergic reaction.

You may need medical attention.

If any of the following happen, stop taking IRBESARTAN HCTZ AMNEAL and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- swelling to the face, lips, tongue or throat which may cause difficulty in swallowing or breathing If you have them, you may have a serious allergic reaction to IRBESARTAN HCTZ AMNEAL
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash. If you have them, you may have a serious allergic reaction

to IRBESARTAN HCTZ AMNEAL

- 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.

These are serious side effects. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Other side effects not listed above may occur in some patients. If you notice any other unwanted effects, you should tell your doctor or pharmacist and ask for their advice.

After using IRPRESTAN HCTZ

Storage

Keep IRBESARTAN HCTZ AMNEAL 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.

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

Do not store IRBESARTAN HCTZ AMNEAL or any other medicine in the bathroom or near a sink.

Do not leave IRBESARTAN HCTZ AMNEAL in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking IRBESARTAN HCTZ AMNEAL, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

IRBESARTAN HCTZ AMNEAL comes in 3 strengths of tablets:

- IRBESARTAN HCTZ AMNEAL 150/12.5 - Pink, oval tablet with 'H' on one side and 'I' on the other side
- IRBESARTAN HCTZ AMNEAL 300/12.5 - Pink, oval tablet with 'H' on one side and 'I' on the other side
- IRBESARTAN HCTZ AMNEAL 300/25 - Dark pink, oval tablet with H on one side and 'I' on the other side.

Each pack contains 30 tablets.

Ingredients

The active ingredients in IRBESARTAN HCTZ AMNEAL are irbesartan and hydrochlorothiazide.

- each IRBESARTAN HCTZ AMNEAL 150/12.5 tablet contains 150 mg of irbesartan and 12.5 mg of hydrochlorothiazide
- each IRBESARTAN HCTZ AMNEAL 300/12.5 tablet contains 300 mg of irbesartan and 12.5 mg of hydrochlorothiazide
- each IRBESARTAN HCTZ AMNEAL 300/25 tablet contains 300 mg of irbesartan and 25 mg of hydrochlorothiazide.

The tablets also contain:

- mannitol
- povidone
- microcrystalline cellulose
- croscarmellose sodium
- colloidal anhydrous silica
- magnesium stearate
- Opadry II 85F34353 Pink (ARTG 107713, 150/12.5 mg tablet only)
- Opadry II 85F34229 Pink (ARTG 107715, 300/12.5 mg tablet only)

- Opadry II 85F34230 Pink (ARTG 107714, 300/25 mg tablet only).

The tablets do not contain lactose, gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Amneal Pharma Australia Pty Ltd
12 River Street
South Yarra VIC 3141
Australia

Australian registration numbers:

IRBESARTAN HCTZ AMNEAL 150/12.5 - AUST R 189375

IRBESARTAN HCTZ AMNEAL 300/12.5 - AUST R 189385

IRBESARTAN HCTZ AMNEAL 300/25 - AUST R 189388

Date of preparation:

July 2016