

Irbesartan Amneal

contains the active ingredient irbesartan

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about IRBESARTAN 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 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 IRBESARTAN AMNEAL is used for

IRBESARTAN AMNEAL lowers high blood pressure, also called 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 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.

IRBESARTAN AMNEAL is also used in the treatment of kidney disease in patients with high blood pressure and type 2 diabetes.

IRBESARTAN AMNEAL 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 AMNEAL blocks angiotensin-II and therefore relaxes your blood vessels. This helps to lower your blood pressure.

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

Your doctor may have prescribed IRBESARTAN AMNEAL for another reason.

Ask your doctor if you have any questions about why IRBESARTAN AMNEAL has been prescribed for you.

IRBESARTAN AMNEAL is available only with a doctor's prescription.

Before you take IRBESARTAN AMNEAL

Do not take IRBESARTAN 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
It is not known if IRBESARTAN AMNEAL passes into breast milk, therefore it is not recommended to be taken while you are breast-feeding.
- you are allergic to irbesartan 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
- 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 AMNEAL, talk to your doctor.

IRBESARTAN 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 AMNEAL should not be used during pregnancy or while breastfeeding
- you have recently had excessive vomiting or diarrhoea
- you suffer from any medical conditions especially:
 - kidney problems, or you have had a kidney transplant or dialysis
 - heart problems
 - liver problems, or have had liver problems in the past
 - diabetes
 - high levels of potassium in your blood
- 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.

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

Taking 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 medicines for high blood pressure
- fluid 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 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 AMNEAL has on reducing blood pressure.
- a medicine containing aliskiren.
Taking IRBESARTAN AMNEAL with aliskiren may affect your blood pressure, electrolyte balance and your kidney function.

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

How to take IRBESARTAN AMNEAL

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

How much to take

The dose varies from patient to patient.

Your doctor will tell you how many tablets to take each day. Usually patients start with one 150 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 AMNEAL should be reached about 4-6 weeks after starting treatment.

Depending on how your blood pressure responds, your daily dose of IRBESARTAN AMNEAL may need to be increased.

Most patients take either 150mg or 300mg each day.

In patients with high blood pressure and type 2 diabetes, 300 mg once daily is the preferred maintenance dose for the treatment of associated kidney disease.

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

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

When to take it:

You should try to take your daily dose of IRBESARTAN AMNEAL at about the same time each day.

Taking your IRBESARTAN AMNEAL tablets at the same time each day will have

the best effect. It does not matter whether you take IRBESARTAN AMNEAL tablets before or after food.

How long to take it:

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

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

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much IRBESARTAN 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 IRBESARTAN AMNEAL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much IRBESARTAN AMNEAL, you may feel dizzy or lightheaded.

While you are taking IRBESARTAN AMNEAL

Things you must do

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

Have your blood pressure checked when your doctor tells you to, to make sure IRBESARTAN AMNEAL is working.

Before starting any new medicine, tell your doctor or pharmacist that you are taking IRBESARTAN AMNEAL.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking IRBESARTAN AMNEAL.

Get up slowly when getting out of bed or standing up. You may feel light-headed or dizzy while taking IRBESARTAN AMNEAL, especially if you are also taking a diuretic (fluid tablet). 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. This problem is not common. If it occurs talk to your doctor.

If you plan to have surgery or other treatment, including dental surgery, that needs a general anaesthetic, tell your doctor or dentist that you are taking IRBESARTAN AMNEAL.

Make sure you drink enough water during exercise and hot weather when you are taking IRBESARTAN AMNEAL, especially if you sweat a lot. If you do not

drink enough water while taking IRBESARTAN 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 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 use IRBESARTAN AMNEAL to treat any other conditions unless your doctor tells you to.

Do not give IRBESARTAN AMNEAL 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 AMNEAL affects you.

As with many other medicines used to treat high blood pressure, IRBESARTAN AMNEAL may cause dizziness or light-headedness in some people. Make sure you know how you react to IRBESARTAN 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 lightheadedness may be worse.

Side effects

IRBESARTAN 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 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
- nausea/vomiting

These are common side effects. They 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
- 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.

These are uncommon but 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 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
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash.

These are very rare but serious side effects. If you have them you have had a serious allergic reaction to IRBESARTAN AMNEAL. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using IRBESARTAN AMNEAL

Storage

Keep IRBESARTAN 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 AMNEAL or any other medicine in the bathroom or near a sink.

Do not leave IRBESARTAN 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 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 AMNEAL comes in 3 strengths of tablets:

- IRBESARTAN AMNEAL 75 - White, oval tablet with 'I' on one side and '75' on the other side
- IRBESARTAN AMNEAL 150 - White, oval tablet with 'I' on one side and '150' on the other side
- IRBESARTAN AMNEAL 300 - White, oval tablet with 'I' on one side and '300' on the other side.

Each pack contains 30 tablets.

Ingredients

The active ingredient in IRBESARTAN AMNEAL is irbesartan.

- each IRBESARTAN AMNEAL 75 tablet contains 75 mg of irbesartan
- each IRBESARTAN AMNEAL 150 tablet contains 150 mg of irbesartan
- each IRBESARTAN AMNEAL 300 tablet contains 300 mg of irbesartan.

The tablets also contain:

- microcrystalline cellulose

- magnesium stearate
- croscarmellose sodium
- hypromellose
- mannitol
- colloidal anhydrous silica
Opadry 20F280002 white (ARTG
109119).

The tablets do not contain 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 AMNEAL 75 - AUST R
223014

IRBESARTAN AMNEAL 150 - AUST R
223015

IRBESARTAN AMNEAL 300 - AUST R
223016

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