

Irbesartan AN capsules

Irbesartan

Consumer Medicine Information

This leaflet answers some common questions about Irbesartan AN.

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 AN 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 AN is used for

Irbesartan AN lowers 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 often 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 AN. 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 AN is also used in the treatment of kidney disease in patients with high blood pressure and type 2 diabetes.

How Irbesartan AN works

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

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

Your doctor may have prescribed Irbesartan AN for another reason.

Ask your doctor if you have any questions about why Irbesartan AN has been prescribed for you.

Irbesartan AN is available only with a doctor's prescription.

Before you take Irbesartan AN

When you must not take it

Do not take Irbesartan AN if:

- **You are allergic to medicines containing irbesartan or any of the ingredients listed at the end of this leaflet.**
- **You are pregnant.** Irbesartan AN may harm your developing baby if you take it during pregnancy.
- **You are breastfeeding.** It is not known if Irbesartan AN passes into breast milk, therefore it is recommended that you do not take it if you are breastfeeding.
- **The expiry date on the pack has passed.**
- **The packaging is torn or shows signs of tampering.**

Irbesartan AN should not be given to children.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives or any of the ingredients listed at the end of this leaflet, including lactose.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Tell your doctor if you are pregnant or plan to become pregnant.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- kidney problems
- heart problems
- liver problems
- recent excessive vomiting or diarrhoea.

Tell your doctor if you are restricting salt intake in your diet.

Tell your doctor if you plan to have surgery (even at the dentist) that needs a general anaesthetic.

If you have not told your doctor about any of the above, tell them before you start taking Irbesartan AN.

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.

Some medicines may be affected by Irbesartan AN, or may affect how well it works. These include:

- other medicines for high blood pressure
- fluid tablets or diuretics
- lithium or lithium containing medicines (for example Lithicarb)
- potassium tablets (for example Span-K, Slow-K, Mag-K)
- potassium containing salt substitutes (for example Pressor-K)

- anti-inflammatory medicines, used to relieve pain, swelling and other symptoms of inflammation, including arthritis. These include nonsteroidal anti-inflammatory agents - NSAIDs (for example Voltaren, Indocid) and COX-2 inhibitors (for example Celebrex).

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

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Irbesartan AN.

How to take Irbesartan AN

How much to take

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-GA should be reached about 4-6 weeks after starting treatment.

Depending on how your blood pressure responds, your daily dose of Irbesartan AN may need to be increased. Most patients take either 150 mg or 300 mg each day.

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

Follow all directions given to you by your doctor and pharmacist carefully. Ask your doctor or pharmacist if you are unsure of the correct dose for you.

How to take it

Swallow the tablets whole with a glass of water.

It does not matter whether you take Irbesartan AN tablets before or after food.

When to take it

Take Irbesartan AN at about the same time each day.

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

How long to take it

Continue taking Irbesartan AN until your doctor tells you to stop.

Irbesartan AN helps to control your high blood pressure, but it does not cure it. Therefore Irbesartan AN must be taken every day.

To help you remember to take your tablets each day, Irbesartan AN tablets are supplied in a Calendar pack with the foil backing marked with the days of the week. This is just a way to 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" at the end of the blister strip. 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.

If you forget to take it

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.

How long to take it for

Irbesartan AN helps control your high blood pressure but does not cure it. To properly control your condition, Irbesartan AN must be taken every day.

Keep taking Irbesartan AN for as long as your doctor recommends.

If you take too much Irbesartan AN (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 AN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Irbesartan AN you may feel dizzy or lightheaded.

While you are taking Irbesartan AN

Things you must do

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

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Irbesartan AN.

If you become pregnant while taking Irbesartan AN, tell your doctor immediately.

If you plan to have surgery, including dental surgery, that needs a general anaesthetic, tell your doctor or dentist that you are taking Irbesartan AN.

Visit your doctor regularly so they can monitor your blood pressure and ensure that Irbesartan AN is working for you.

Make sure you drink enough water during exercise and hot weather when you are taking Irbesartan AN.

If you do not drink enough water while taking Irbesartan AN, 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 Irbesartan AN, tell your doctor.

You may lose too much water and salt and your blood pressure may drop too much.

If you feel lightheaded or dizzy after taking your first dose of Irbesartan AN, or when your dose is increased, tell your doctor immediately.

Things you must not do

Do not use Irbesartan AN to treat any other conditions unless your doctor tells you to.

Do not give Irbesartan AN to anyone else, even if they have the same condition as you.

Do not stop taking Irbesartan AN or lower the dose without checking with your doctor.

Things to be careful of

Be careful getting up from a sitting or lying position.

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help. This problem can be more common if you are also taking a diuretic (fluid tablets). 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.

Be careful driving or operating machinery until you know how Irbesartan AN affects you.

Irbesartan AN may cause drowsiness, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

If you drink alcohol, dizziness or lightheadedness may be worse.

Things that would be helpful for lowering your blood pressure:

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

1. **Alcohol**

Your doctor may advise you to limit your alcohol intake.

2. **Weight**

If you are overweight, your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dieticians help to lose weight.

3. **Diet**

Your doctor may advise you to eat a healthy low-fat diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish.

4. Salt

Your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt in cooking or at the table.

5. Exercise

Regular exercise helps to reduce blood pressure and helps get the heart fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is reasonably flat. Before starting any exercise, ask your doctor about the best kind of programme for you.

6. Smoking

Your doctor may advise you to stop smoking or at least cut down.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Irbesartan AN.

Like all other medicines, Irbesartan AN may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- headache
- dizziness or lightheadedness (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 or weakness
- 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
- symptoms that may indicate liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine.

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 AN 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 nettlerash.

These are very rare but serious side effects. If you have them you have had a serious allergic reaction to Irbesartan AN. 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 AN

Storage

Keep your Irbesartan AN tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep Irbesartan AN 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 AN or any other medicine in the bathroom or near a sink. Do not leave in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Irbesartan AN, 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 AN is presented in PVC/PVDC/Al blisters pack of 30 tablets.

- Irbesartan AN 75 mg tablets (AUST R 192795) - White to off-white, oval and biconvex tablet, debossed with "L172" on one side and "75" on the other side.
- Irbesartan AN 150 mg tablets (AUST R 192797) - White to off-white, oval and biconvex tablet, debossed with "L173" on one side and "150" on the other side

- Irbesartan AN 300 mg tablets (AUST R 192801) - White to off-white, oval and biconvex tablet, debossed with "L174" on one side and "300" on the other side.

Ingredients

Active ingredient

Irbesartan.

- each Irbesartan AN 75 mg tablet contains 75 mg of irbesartan
- each Irbesartan AN 150 mg tablet contains 150 mg of irbesartan
- each Irbesartan AN 300 mg tablet contains 300 mg of irbesartan.

The tablets also contain:

- Microcrystalline cellulose
- Lactose
- Croscarmellose sodium
- Povidone
- Magnesium stearate
- OPADRY II complete film coating system 30F58652
WHITE

Sponsor

Amneal Pharma Australia Pty Ltd

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Australia.

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