

IRBESARTAN GH

(irbesartan) film-coated tablet

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking Irbesartan GH. This leaflet answers some common questions about Irbesartan GH.

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

Always follow the instructions that your doctor and pharmacist give you about Irbesartan GH.

If you have any concerns about taking Irbesartan GH, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to refer to it again later.

What Irbesartan GH is used for

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

What Irbesartan GH does and how it works

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

Irbesartan GH slows the decrease of kidney function in patients with

high blood pressure and type 2 diabetes.

Ask your doctor if you have any questions about this medicine.

Your doctor may have prescribed Irbesartan GH for another use

Before you take Irbesartan GH

When you must not take it

Do not take Irbesartan GH 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 GH 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 at the end of this leaflet.
- you are diabetic or have kidney problems and are being treated with an ACE inhibitor, any aliskiren-containing medicines or a group of medicines known as AIIRAs (medicines also used to treat high blood pressure).
- the packaging is torn or shows signs of tampering.
- the expiry date printed 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 GH, talk to your doctor.

Irbesartan GH should not be given to children.

Before you start to take it

Tell your doctor if:

- you are pregnant, or intend to become pregnant, or plan to breast-feed. Irbesartan GH should not be used during pregnancy or while breast-feeding.
- 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 have allergies to any other medicines 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 GH.

Taking other medicines

Tell your doctor if you are taking or intend to take any other medicines, including medicines that you buy without a prescription from your 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;
- 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. These are used to relieve pain, swelling and other symptoms of inflammation, including arthritis and include non-steroidal anti-inflammatory agents (NSAIDs, for example Voltaren, Indocid) and COX-2 inhibitors (for example Celebrex). Taking a combination of Irbesartan GH and an anti-inflammatory medicine alone or with a thiazide diuretic (fluid tablet) may damage your kidneys. It may also reduce the effect Irbesartan GH has on reducing blood pressure;
- a medicine containing aliskiren. Taking Irbesartan GH 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 GH

The tablets should be taken regularly as directed by your doctor.

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 GH should be reached

about 4-6 weeks after starting treatment.

Depending on how your blood pressure responds, your daily dose of Irbesartan GH 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 the treatment of associated kidney disease.

Follow all directions given to you by your doctor 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 it

The tablets should be swallowed with a glass of water.

When to take it

You should try to take your daily dose of Irbesartan GH at about the same time each day. Taking your Irbesartan GH at the same time each day will have the best effect.

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

How long to take it

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

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 it as soon as you remember, and 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 missed dose.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (phone 13 11 26) or go to the Accident and Emergency department at your nearest hospital, if you or anyone else may have taken too much Irbesartan GH.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Irbesartan GH you will probably feel light-headed or dizzy.

While you are taking Irbesartan GH

Things you must do

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

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

If you are about to start on any new medicine, tell your doctor and pharmacist that you are taking Irbesartan GH.

Get up slowly when getting out of bed or standing up. You may feel light-headed or dizzy while taking Irbesartan GH, 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 (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking Irbesartan GH.

Make sure you drink enough water during exercise and hot weather when you are taking Irbesartan GH, especially if you sweat a lot. If you do not drink enough water while taking Irbesartan GH, 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 GH, 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 GH 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 GH affect you. As with many other medicines used to treat high blood pressure, Irbesartan GH may cause dizziness or light-headedness in some people.

Make sure you know how you react to Irbesartan GH 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.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel

well while you are taking Irbesartan GH.

Irbesartan GH 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 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;
- symptoms that may indicate low platelet count such as easy or excessive bruising, bleeding from gums or nose, prolonged bleeding from cuts and blood in urine or stools.

These are serious side effects. Skin rash and itchiness may be symptoms of an allergic reaction. You may need medical attention. These side effects are not common.

If any of the following happen, stop taking Irbesartan GH and tell your doctor immediately or go to Accident and Emergency Department at your nearest hospital:

- swelling of 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.

These are serious side effects. If you have them you may have had a serious allergic reaction to Irbesartan GH. 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 or advise.

After taking Irbesartan GH

Storage

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

Do not store Irbesartan GH or any other medicine in the bathroom or near a sink. Do not leave them in a car or on a window sill. Heat and dampness can destroy some medicines.

Keep all medicines out of the reach of children. 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 Irbesartan GH or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

Irbesartan GH 75 mg tablets are white to off-white, oval shaped, film-coated tablets embossed with “I1” on one side and plain on the other side.

Irbesartan GH 150 mg tablets are white to off-white, oval shaped, film-coated tablets embossed with “I2” on one side and plain on the other side.

Irbesartan GH 300 mg tablets are white to off-white, oval shaped, film-coated tablets embossed with “I3” on one side and plain on the other side.

Irbesartan GH tablets are supplied in PVC/PVDC/aluminium blister packs of 14, 28, 30, 56 and 98 tablets.

Not all pack sizes are marketed.

Ingredients

Active ingredients

Each Irbesartan GH tablet contains 75 mg, 150 mg or 300 mg irbesartan.

Other ingredients

- mannitol;
- crospovidone;
- colloidal anhydrous silica;
- sodium lauryl sulphate;
- povidone;
- magnesium stearate;
- purified water;
- Opadry complete film-coating system 03B28796 White (contains hypromellose, titanium dioxide E 171 and macrogol 400).

Australian Registration Numbers

Irbesartan GH 75 mg: AUST R 191408

Irbesartan GH 150 mg: AUST R 191404

Irbesartan GH 300 mg: AUST R 191084

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