

# IRBESARTAN-WGR

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using IRBESARTAN-WGR?

Irbesartan-WGR contains the active ingredient irbesartan. Irbesartan-WGR is used to treat high blood pressure and is also used in the treatment of kidney disease in patients with high blood pressure and type 2 diabetes. For more information, see Section [1. Why am I using IRBESARTAN-WGR?](#) in the full CMI.

### 2. What should I know before I use IRBESARTAN-WGR?

Do not use if you have ever had an allergic reaction to Irbesartan-WGR or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use IRBESARTAN-WGR?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with IRBESARTAN-WGR and affect how it works. Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use IRBESARTAN-WGR?

- Your doctor will tell you how many tablets to take each day. The standard dose is one 150 mg tablet per day. This dose may be increased to a 300 mg once per day.
- Swallow the table whole with a glass of water and take Irbesartan-WGR at about the same time each day.

More instructions can be found in Section [4. How do I use IRBESARTAN-WGR?](#) in the full CMI.

### 5. What should I know while using IRBESARTAN-WGR?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor or dentist you visit that you are taking Irbesartan-WGR.</li><li>If you become pregnant or plan to breastfeed while taking Irbesartan-WGR tell your doctor immediately</li><li>If you are to be started on any new medicine, tell your doctor and pharmacist you are taking Irbesartan-WGR</li><li>If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Irbesartan-WGR.</li><li>Make sure you drink enough water during exercise and hot weather when you are taking Irbesartan-WGR.</li><li>If you have excessive vomiting and/or diarrhoea while taking Irbesartan-WGR, tell your doctor.</li><li>If you feel lightheaded or dizzy when your dose is increased, tell your doctor immediately</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not stop using this medicine or change the dose. Do not skip meals while taking IRBESARTAN-WGR.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful driving or operating machinery until you know how this medicine affects you. Irbesartan-WGR may cause dizziness or light-headedness in some people. If this occurs do not drive.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>If you drink alcohol, dizziness or light-headedness may be worse.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep Irbesartan-WGR tablets in a cool dry place where the temperature stays below 25°C</li><li>Keep your tablets in the packaging until it is time to take them</li></ul>

For more information, see Section [5. What should I know while using IRBESARTAN-WGR?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects: headache, dizziness or light-headedness, unusual tiredness or weakness, fatigue, nausea/vomiting. Serious side effects: 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 (hives or nettle rash). Common side effects: headache; dizziness or light-headedness (vertigo); unusual tiredness or weakness, fatigue; nausea/vomiting.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# IRBESARTAN-WGR

Active ingredient: *Irbesartan*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using IRBESARTAN-WGR.

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

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

**You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using IRBESARTAN-WGR.**

Keep this leaflet with your medicine. You may need to read it again.

Where to find information in this leaflet:

- [1. Why am I using IRBESARTAN-WGR?](#)
- [2. What should I know before I use IRBESARTAN-WGR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use IRBESARTAN-WGR?](#)
- [5. What should I know while using IRBESARTAN-WGR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using IRBESARTAN-WGR?

**IRBESARTAN-WGR contains the active ingredient irbesartan.**

Irbesartan-WGR belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin II is a substance produced in the body that causes blood vessels to narrow. Irbesartan-WGR blocks angiotensin-II and therefore widens your blood vessels,

making it easier for your heart to pump blood throughout your body. This helps to lower your blood pressure. Irbesartan-WGR also slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

**Irbesartan-WGR is used to treat high blood pressure, which doctors call hypertension. Irbesartan-WGR is also used in the treatment of kidney disease in patients with high blood pressure and type 2 diabetes.**

## 2. What should I know before I use IRBESARTAN-WGR?

### Warnings

**Do not use IRBESARTAN-WGR if:**

- you are allergic to irbesartan, or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can take
- this medicine.
- you are pregnant (or think you may be pregnant) or are planning to become pregnant.
- you are breast-feeding. It is not known if Irbesartan-WGR passes into breast milk, therefore it is recommended that you not take it while you are breast-feeding
- you have diabetes or have kidney problems and are being treated with medicines that lower blood pressure such as an ACE inhibitor, any medicines containing aliskiren or medicines that belong to a group of medicines known as Angiotensin-II receptor antagonists (medicines also used to treat high blood pressure)

### Check with your doctor if you:

- have any other medical conditions
- have had recent excessive vomiting or diarrhoea
- have kidney problems, or you have had a kidney transplant or dialysis
- have heart problems
- have liver problems, or have had liver problems in the past
- have diabetes
- have high levels of potassium in your blood
- are strictly restricting your salt intake
- take any medicines for any other condition
- are pregnant or intend to become pregnant
- if you are breast feeding or plan to breastfeed
- plan to have surgery (even at the dentist) that needs a general anaesthetic
- have allergies to any substances, such as foods, preservatives, or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

- Check with your doctor if you are pregnant or intend to become pregnant. Do not take Irbesartan-WGR if you are pregnant or intend to become pregnant.
- Talk to your doctor if you are breastfeeding or intend to breastfeed. Do not take Irbesartan-WGR if you are breastfeeding.

### Use in Children

- Irbesartan-WGR should not be given to children.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Tell your doctor if you are taking or plan to take any of the following:**

- other medicines to treat high blood pressure
- potassium supplements or, potassium-containing salt substitutes (you may need to have regular blood tests)
- diuretics
- medicines containing lithium (you may need to have regular blood tests)
- non-steroidal anti-inflammatory medicine such as diclofenac, ibuprofen) and COX- 2 inhibitors (for example celecoxib) These medicines may be used to relieve pain, swelling and other symptoms of inflammation including arthritis. Taking Irbesartan-WGR and an anti-inflammatory medicine alone or with a thiazide diuretic (fluid tablet) may damage your kidneys. It may also reduce the effect Irbesartan-WGR has on lowering blood pressure.
- medicines taken to treat diabetes such as repaglinide. Irbesartan-WGR might lower your blood glucose levels.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Irbesartan-WGR.**

### 4. How do I use IRBESARTAN-WGR?

#### How much to take

- The usual starting dose is 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-WGR should be reached about 4 to 6 weeks after starting treatment.
- Depending on how your blood pressure responds, your
- daily dose of Irbesartan-WGR may need to be increased. Most patients take either 150 mg or 300 mg once a day.
- In patients with high blood pressure and type 2 diabetes,
- 300 mg once a day is the preferred maintenance dose for slowing the progression of associated kidney disease.
- Ask your doctor or pharmacist if you are unsure of the
- correct dose for you. They will tell you exactly how much to take.
- Follow the instructions provided and take Irbesartan-WGR until your doctor tells you to stop.

#### When to take IRBESARTAN-WGR

- Take Irbesartan-WGR at about the same time each day.

### How to take IRBESARTAN-WGR

- Swallow the tablet whole with a glass of water. It does not matter whether you take Irbesartan-WGR tablets before or after food.
- Continue taking Irbesartan-WGR until your doctor tells you to stop.
- To help you remember to take your tablets each day, Irbesartan-WGR 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 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 the tablets are taken. Commence the next strip at "START" and continue as before.

#### If you forget to use IRBESARTAN-WGR

Irbesartan-WGR should be used regularly at the same time each day. If you miss your dose at the usual time.

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

#### If you use too much IRBESARTAN-WGR

If you think that you have used too much Irbesartan-WGR, you may need urgent medical attention. If you take too many Irbesartan-WGR tablets you will probably feel lightheaded or dizzy.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

**If you take too many Irbesartan-WGR tablets you will probably feel lightheaded or dizzy.**

### 5. What should I know while using IRBESARTAN-WGR?

#### Things you should do

- Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Irbesartan-WGR
- Tell your doctor immediately if you become pregnant while taking Irbesartan-WGR
- Have your blood pressure checked when your doctor tells you to, to make sure Irbesartan-WGR is working
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Irbesartan-WGR

- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Irbesartan-WGR. Your blood pressure may drop suddenly
- Make sure you drink enough water during exercise and hot weather when you are taking Irbesartan-WGR, especially if you sweat a lot. If you do not drink enough water while taking Irbesartan-WGR, 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.
- Tell your doctor if you have excessive vomiting and/or diarrhoea while taking Irbesartan-WGR. You may lose too much water and salt and your blood pressure may drop too much.
- Tell your doctor immediately if you feel lightheaded or dizzy after taking your first dose of Irbesartan-WGR, or when your dose is increased.

### Things you should not do

- Do not give Irbesartan-WGR tablets to anyone else, even if they have the same condition as you
- Do not take Irbesartan-WGR to treat any other complaints unless
- your doctor or pharmacist tells you to
- Do not stop taking Irbesartan-WGR, or lower the dosage, without checking with your doctor

### Things to be careful of

- If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.
- 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 problem continues or gets worse, talk to your doctor.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how IRBESARTAN-WGR affects you.**

As with many other medicines used to treat high blood pressure, Irbesartan-WGR may cause dizziness or light-headedness in some people. If this occurs do not drive.

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

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

If you drink alcohol, dizziness or light-headedness may be worse.

### Looking after your medicine

- Keep Irbesartan-WGR tablets in a cool dry place where the temperature stays below 25°C
- Keep your tablets in the blister pack until it is time to take them

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• headache</li> <li>• dizziness or light-headedness (vertigo)</li> <li>• unusual tiredness or weakness, fatigue</li> <li>• nausea/vomiting</li> <li>• low blood glucose levels</li> <li>• decreased number of red blood cells (anaemia – symptoms include tiredness, headaches, being short of breath when exercising, dizziness and looking pale)</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p><b>They are generally mild and do not normally require treatment to be interrupted.</b></p>
<ul style="list-style-type: none"> <li>• stomach upset such as feeling sick (nausea), heartburn</li> <li>• constipation or a feeling of fullness in the stomach</li> <li>• headache</li> <li>• tiredness.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• skin rash or itchiness</li> <li>• aching muscles, not caused by</li> </ul>	<p><b>Call your doctor straight away,</b></p>

<p>exercise</p> <ul style="list-style-type: none"> <li>• muscle pain or weakness</li> <li>• blood tests may show raised levels of an enzyme that measures the breakdown of muscle (creatine phosphokinase)</li> <li>• buzzing, ringing or other persistent noise in the ear</li> <li>• symptoms that may indicate kidney disease, such as passing little or no urine, drowsiness, nausea, vomiting, breathlessness, loss of appetite and weakness</li> <li>• symptoms that may indicate high</li> <li>• potassium levels in the blood, such as nausea, diarrhoea, muscle weakness, change in heart rhythm</li> <li>• yellowing of the skin and/or eyes, also called jaundice</li> <li>• symptoms that may indicate liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing</li> <li>• of the skin and eyes and dark coloured urine</li> </ul>	<p><b>you may need medical attention</b></p>
<p>Allergy-related symptoms:</p> <ul style="list-style-type: none"> <li>• swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing</li> <li>• severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash</li> </ul>	<p><b>Stop taking Irbesartan-WGR and call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What IRBESARTAN-WGR contains

<p><b>Active ingredient (main ingredient)</b></p>	<p>Each tablet contains 75 mg, 150 mg or 300 mg of irbesartan</p>
<p><b>Other ingredients (inactive ingredients)</b></p>	<ul style="list-style-type: none"> <li>• croscarmellose sodium</li> <li>• lactose monohydrate</li> <li>• magnesium stearate</li> <li>• povidone</li> <li>• OPADRY II complete film coating system 30F58652 WHITE</li> </ul>
<p><b>Potential allergens</b></p>	<p>The tablets contain sugars as lactose.</p>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What IRBESARTAN-WGR looks like

Irbesartan-WGR 75 mg tablets: White to off-white, oval shaped, biconvex, film-coated tablet. Debossed with "L172" on one side and "75" on the other side. Pack size: 30 tablets. AUST R 432157.

Irbesartan-WGR 150 mg tablets: White to off-white, oval shaped, biconvex, film-coated tablet. Debossed with "L173" on one side and "150" on the other side. Pack size: 30 tablets. AUST R 432155.

Irbesartan-WGR 300 mg tablets: White to off-white, oval shaped, biconvex, film-coated tablet. Debossed with "L174" on one side and "300" on the other side. Pack size: 30 tablets. AUST R 432156.

### Who distributes IRBESARTAN-WGR

Wagner Pharmaceuticals Pty Ltd

6 Albert Street

Preston, Victoria, 3072

Tel: 1800 936 140

This leaflet was prepared in August 2024.