

Irbesartan Sandoz® Tablets

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 taking Irbesartan Sandoz?

Irbesartan Sandoz contains the active ingredient irbesartan. Irbesartan Sandoz 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 taking Irbesartan Sandoz?](#) in the full CMI.

2. What should I know before I take Irbesartan Sandoz?

Do not use if you have ever had an allergic reaction to Irbesartan Sandoz 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 take Irbesartan Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Irbesartan Sandoz and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take Irbesartan Sandoz?

- 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 tablet whole with a glass of water and take Irbesartan Sandoz at about the same time each day.

More instructions can be found in Section [4. How do I take Irbesartan Sandoz?](#) in the full CMI.

5. What should I know while taking Irbesartan Sandoz?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Irbesartan Sandoz.If you become pregnant or plan to breastfeed while taking Irbesartan Sandoz tell your doctor immediately.If you are about to be started on any new medicine, tell your doctor and pharmacist you are taking Irbesartan Sandoz.If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Irbesartan Sandoz.Make sure you drink enough water during exercise and hot weather when you are taking Irbesartan Sandoz.If you have excessive vomiting and/or diarrhoea while taking Irbesartan Sandoz, tell your doctor.If you feel lightheaded or dizzy when you dose is increased, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine, or lower the dosage, without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how Irbesartan Sandoz affects you. Irbesartan Sandoz may cause dizziness or light-headedness in some people. If this occurs do not drive.
Drinking alcohol	<ul style="list-style-type: none">If you drink alcohol, dizziness or light-headedness may be worse.
Looking after your medicine	<ul style="list-style-type: none">Keep Irbesartan Sandoz tablets in a cool dry place where the temperature stays below 25°C.Keep your tablets in the packaging until it is time to take them.

For more information, see Section [5. What should I know while taking Irbesartan Sandoz?](#) in the full CMI.

6. Are there any side effects?

Common side effects: headache, dizziness or light-headedness (vertigo), 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). 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 Sandoz® Tablets

Active ingredient(s): *irbesartan*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Irbesartan Sandoz. **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 Sandoz.**

Where to find information in this leaflet:

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

1. Why am I taking Irbesartan Sandoz?

Irbesartan Sandoz contains the active ingredient irbesartan. Irbesartan Sandoz 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 Sandoz 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 Sandoz also slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Irbesartan Sandoz is used to treat high blood pressure, which doctors call hypertension. Irbesartan Sandoz 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 take Irbesartan Sandoz?

Warnings

Do not use Irbesartan Sandoz 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 use this medicine.
- you are pregnant (or think you may be pregnant) or are planning to become pregnant.
- you are breastfeeding. It is not known if Irbesartan Sandoz passes into breast milk, therefore it is recommended that you not take it while you are breastfeeding.
- 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 had 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 breastfeeding 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?](#)

Use in children

Irbesartan Sandoz should not be given to children.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Do not take Irbesartan Sandoz 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 Sandoz if you are breastfeeding.

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 Sandoz and an anti-inflammatory medicine alone or with a thiazide diuretic (fluid tablet) may damage your kidneys. It may also reduce the effect Irbesartan Sandoz has on lowering blood pressure.
- medicines taken to treat diabetes such as repaglinide. Irbesartan Sandoz 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 Sandoz.

4. How do I take Irbesartan Sandoz?

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 Sandoz should be reached about 4 to 6 weeks after starting treatment.
- Depending on how your blood pressure responds, your daily dose of Irbesartan Sandoz 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 Sandoz until your doctor tells you to stop.

When to take Irbesartan Sandoz

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

How to take Irbesartan Sandoz

- Swallow the tablet whole with a glass of water. It does not matter whether you take Irbesartan Sandoz tablets before or after food.
- Continue taking Irbesartan Sandoz until your doctor tells you to stop.
- To help you remember to take your tablets each day, Irbesartan Sandoz 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 take Irbesartan Sandoz

Irbesartan Sandoz should be used regularly at the same time each day.

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 normally would.

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

If you take too much Irbesartan Sandoz

If you think that you have used too much Irbesartan Sandoz, you may need urgent medical attention. If you take too many Irbesartan Sandoz 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.

5. What should I know while taking Irbesartan Sandoz?

Things you should do

- Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Irbesartan Sandoz.
- Tell your doctor immediately if you become pregnant while taking Irbesartan Sandoz.
- Have your blood pressure checked when your doctor tells you to, to make sure Irbesartan Sandoz is working.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Irbesartan Sandoz.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Irbesartan Sandoz. Your blood pressure may drop suddenly.
- Make sure you drink enough water during exercise and hot weather when you are taking Irbesartan Sandoz, especially if you sweat a lot. If you do not drink enough water while taking Irbesartan Sandoz, 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 Sandoz. 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 Sandoz, or when your dose is increased.

Things you should not do

- Do not give Irbesartan Sandoz tablets to anyone else, even if they have the same condition as you.
- Do not take Irbesartan Sandoz to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop taking Irbesartan Sandoz, 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 Sandoz affects you.

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

Make sure you know how you react to Irbesartan Sandoz 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 Sandoz 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.

Keep it where young children cannot reach it.

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"> • headache • dizziness or light-headedness (vertigo) • unusual tiredness or weakness, fatigue • nausea/vomiting • low blood glucose levels • decreased number of red blood cells (anaemia – symptoms include tiredness, headaches, being short of breath when exercising, dizziness and looking pale) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>They are generally mild and do not normally require treatment to be interrupted.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • skin rash or itchiness • aching muscles, not caused by exercise • muscle pain or weakness • blood tests may show raised levels of an enzyme that measures the breakdown of muscle (creatinine phosphokinase) • buzzing, ringing or other persistent noise in the ear • 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, change in heart rhythm • yellowing of the skin and/or eyes, also called jaundice • 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 	<p>Call your doctor straight away, you may need medical attention.</p>

<p>Allergy-related symptoms:</p> <ul style="list-style-type: none"> • 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 or nettle rash 	<p>Stop taking Irbesartan Sandoz 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.</p>
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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. 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 Sandoz contains

Active ingredient (main ingredient)	Each tablet contains 75 mg, 150 mg or 300 mg of irbesartan.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • microcrystalline cellulose • lactose monohydrate • croscarmellose sodium • colloidal anhydrous silica • hypromellose • magnesium stearate • hydroxypropylcellulose • macrogol 6000 • purified talc • titanium dioxide
Potential allergens	<ul style="list-style-type: none"> • lactose monohydrate

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

What Irbesartan Sandoz looks like

Irbesartan Sandoz 75 mg – white, oval biconvex film-coated tablets, marked “75” on one side and scored on the other side. Pack size of 30 tablets (AUST R 167406).

Irbesartan Sandoz 150 mg – white, oval biconvex film-coated tablets, marked “150” on one side and scored on the other side. Pack size of 30 tablets (AUST R 167409).

Irbesartan Sandoz 300 mg – white, oval biconvex film-coated tablets, marked “300” on one side and scored on the other side. Pack size of 30 tablets (AUST R 167407).

Who distributes Irbesartan Sandoz

Irbesartan Sandoz is supplied in Australia by:

Sandoz Pty Ltd

ABN 60 075 449 553

54 Waterloo Road

Macquarie Park, NSW 2113

Tel: 1800 726 369

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