

Irbesartan Medicianz

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 Medicianz?

Irbesartan Medicianz contains the active ingredient irbesartan. Irbesartan Medicianz 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 Medicianz? in the full CMI.

2. What should I know before I use Irbesartan Medicianz?

Do not use if you have ever had an allergic reaction to Irbesartan Medicianz 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 Medicianz? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Irbesartan Medicianz 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 use Irbesartan Medicianz?

- 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 Medicianz at about the same time each day.

More instructions can be found in Section 4. How do I take Irbesartan Medicianz? in the full CMI.

5. What should I know while using Irbesartan Medicianz?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor or dentist you visit that you are taking Irbesartan Medicianz. • If you become pregnant or plan to breastfeed while taking Irbesartan Medicianz tell your doctor immediately • If you are to be started on any new medicine, tell your doctor and pharmacist you are taking Irbesartan Medicianz. • If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Irbesartan Medicianz. • Make sure you drink enough water during exercise and hot weather when you are taking Irbesartan Medicianz. • If you have excessive vomiting and/or diarrhoea while taking Irbesartan Medicianz, tell your doctor. • If you feel lightheaded or dizzy when your dose is increased, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none"> • Do not stop taking Irbesartan Medicianz, 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 Medicianz affects you. Irbesartan Medicianz 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 your Irbesartan Medicianz tablets in the blister pack until it is time to take them. • Keep Irbesartan Medicianz tablets in a cool dry place where the temperature stays below 25°C. Protect from light.

For more information, see Section 5. What should I know while taking Irbesartan Medicianz? 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. These are common side effects. 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 Medicianz

Active ingredient(s): *Irbesartan*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Irbesartan Medicianz. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Irbesartan Medicianz.

Where to find information in this leaflet:

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

1. Why am I using Irbesartan Medicianz?

Irbesartan Medicianz contains the active ingredient irbesartan. Irbesartan Medicianz 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 narrow. Irbesartan Medicianz blocks angiotensin-II and therefore widens your blood vessels. This helps to lower your blood pressure.

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

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

Warnings

Do not use Irbesartan Medicianz 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 Medicianz 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 had recent excessive vomiting or diarrhea
- have any other medical conditions
- 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
- you are lactose intolerant or have had any allergies to any other medicine or any other 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 Medicianz 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 Medicianz 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 Medicianz 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
- diuretics
- medicines containing lithium (you may need to have regular blood tests)
- potassium supplements or, potassium containing salt substitutes (you may need to have regular blood tests)

non steroidal anti-inflammatory medicines 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 Medicianz and an anti-inflammatory medicine alone or with a thiazide diuretic (fluid tablet) may damage your kidneys. It may also reduce the effect Irbesartan Medicianz has on reducing blood pressure.

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 Medicianz.

4. How do I take Irbesartan Medicianz?

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 Medicianz should be reached about 4 to 6 weeks after starting treatment.
- Depending on how your blood pressure responds, your daily dose of Irbesartan Medicianz may need to be increased. Most patients take either 150mg or 300mg once a day.

In patients with high blood pressure and type 2 diabetes, 300mg 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 Medicianz until your doctor tells you to stop.

When to take Irbesartan Medicianz

Take Irbesartan Medicianz at about the same time each day.

How to take Irbesartan Medicianz

- Irbesartan Medicianz helps to control your high blood pressure, but it does not cure it. Therefore Irbesartan Medicianz must be taken every day. Continue taking Irbesartan Medicianz until your doctor tells you to stop.
- Swallow the tablet whole with a glass of water. It does not matter whether you take Irbesartan Medicianz tablets before or after food.
- Continue taking Irbesartan Medicianz until your doctor tells you to stop.

If you forget to take Irbesartan Medicianz

Irbesartan Medicianz 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 take too much Irbesartan Medicianz

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

You should immediately:

- phone the National Poisons Centre on 0800 POISON (0800 764766), 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 Medicianz tablets you will probably feel lightheaded or dizzy.

5. What should I know while taking Irbesartan Medicianz?

Things you should do

- Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Irbesartan Medicianz
Tell your doctor immediately if you become pregnant while taking Irbesartan Medicianz
- Have your blood pressure checked when your doctor tells you to, to make sure Irbesartan Medicianz is working.

- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Irbesartan Medicianz.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Irbesartan Medicianz. Your blood pressure may drop suddenly
- Make sure you drink enough water during exercise and hot weather when you are taking Irbesartan Medicianz, especially if you sweat a lot.
- If you do not drink enough water while taking Irbesartan Medicianz, 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 Medicianz. You may lose too much water and salt and your blood pressure may become too much.

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

Things you should not do

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

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

Make sure you know how you react to Irbesartan Medicinz 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 your Irbesartan Medicinz 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.

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

Store it in a cool dry place (where the temperature stays below 25°C) 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.

Do not leave them near a radiator, in a car on hot days or on a window sill.

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.

When to discard your medicine

If your doctor tells you to stop taking Irbesartan Medicinz or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

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 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you. They are generally mild and do not 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 	<p>Call your doctor straight away, You may need medical</p>

<ul style="list-style-type: none"> • buzzing, ringing or other persistent noise in the ear • 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, 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 	<p>attention</p> <p>These side effects are not common</p>
<p>Allergy-related symptoms:</p> <ul style="list-style-type: none"> • 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 	<p>Stop taking Irbesartan Medicianz 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>

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed here may also 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 Medicianz contains

<p>Active ingredient (main ingredient)</p>	<p>Irbesartan Medicianz 75 mg tablets - 75 mg irbesartan per tablet.</p> <p>Irbesartan Medicianz 150 mg tablets - 150 mg irbesartan per tablet.</p> <p>Irbesartan Medicianz 300 mg tablets - 300 mg irbesartan per tablet.</p>
<p>Other ingredients (inactive ingredients)</p>	<p>Irbesartan Medicianz tablets also contain lactose monohydrate, sodium starch glycollate type B, polysorbate 80, hypromellose, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate, macrogol 6000</p>

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

What Irbesartan Medicianz looks like

Irbesartan Medicianz 75 mg tablets - White to off-white, oval, biconvex, film-coated tablets, engraved with '75' on one face and plain on the other face.

Pack size: Blister packs of 30 tablets.

Irbesartan Medicianz 150 mg tablets - White to off-white, oval, biconvex, film-coated tablets, engraved with '150' on one face and plain on the other face.

Pack size: Blister packs of 30 tablets.

Irbesartan Medicianz 300 mg tablets - White to off-white, oval, biconvex, film-coated tablets, engraved with '300' on one face and plain on the other face.

Pack size: Blister packs of 30 tablets.

Who distributes Irbesartan Medicianz

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This information in no way replaces the advice
of your doctor or pharmacist.

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