

Irbesartan Sandoz®

Irbesartan tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Irbesartan Sandoz.

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

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT IRBESARTAN SANDOZ IS USED FOR

This medicine is used to lower 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) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are often no symptoms of high blood pressure. The only way of knowing that you have high blood pressure is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems, such as stroke, heart disease and kidney failure. This medicine is also used in the treatment of kidney disease in patients with high blood pressure and type 2 diabetes.

This medicine contains the active ingredient irbesartan.

Irbesartan 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

There is no evidence that this medicine is addictive.

BEFORE YOU TAKE IRBESARTAN SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- irbesartan, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.

- any other similar medicines.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you are pregnant or are planning to become pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

It is not known if the active ingredient in Irbesartan Sandoz passes into breast milk, therefore it is recommended that you do not take it while you are breastfeeding.

Do not give this medicine to children. Safety and effectiveness in children have not been established.

Do not take this medicine if 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).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- recent excessive vomiting or diarrhoea.
- 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.

Tell your doctor if you are or intend to become pregnant or plan to breast-feed. Irbesartan Sandoz should not be used during pregnancy or while breast-feeding.

Tell your doctor if you are strictly restricting your salt intake.

Irbesartan Sandoz contains lactose.

If you have been told by your doctor that you have intolerance to some sugars, tell your doctor before taking it.

If you have not told your doctor about any of the above, tell him/her before you start taking Irbesartan Sandoz.

Taking other medicines

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

Some medicines and Irbesartan Sandoz may interfere with each other. These include:

- other medicines used to treat high blood pressure
- diuretics, also known as water or fluid tablets
- anti-inflammatory drugs, medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis, including non-steroidal anti-inflammatory drugs (NSAIDs) and COX-2 inhibitors (for example Celebrex).
- combination treatment of irbesartan, thiazide diuretics and anti-inflammatory drugs
- potassium-containing salt substitutes
- potassium tablets (for example Span-K, Slow-K, Mag-K)
- lithium or lithium containing medicine (for example Lithicarb), a medicine used to treat mood swings and some types of depression
- a medicine containing aliskiren. Taking Irbesartan Sandoz with aliskiren may affect your blood pressure, electrolyte balance and your kidney function.

These medicines may be affected by Irbesartan Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

HOW TO TAKE IRBESARTAN SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets to take each day.

The usual starting dose is one 150mg tablet once a day. Sometimes a lower starting dose is needed. Your doctor will tell you if this is necessary.

The full blood pressure lowering effect should be reached about 4-6 weeks after starting treatment.

Depending on how your blood pressure responds, your doctor may increase your daily dose to 150mg or 300mg.

If you have high blood pressure and type 2 diabetes, 300mg once daily is the usual 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 they give you.

If you take the wrong dose, Irbesartan Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

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

If you need to break the tablet, hold it with both hands and snap along break line.

When to take Irbesartan Sandoz

Take your medicine at about the same time each day.

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

How long to take Irbesartan Sandoz

Continue taking your medicine for as long as your doctor tells you.

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

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Irbesartan Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include light-headedness or dizziness.

WHILE YOU ARE TAKING IRBESARTAN SANDOZ

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Irbesartan Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

If you plan to have surgery or other treatment that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

Your blood pressure may drop suddenly.

Make sure you drink enough water during exercise and hot weather when you are taking this medicine, especially if you sweat a lot.

If you do not drink enough water while taking this medicine, 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 this medicine, tell your doctor.

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

Get up slowly when getting out of bed or standing up. You may feel light-headed or dizzy while taking Irbesartan Sandoz, 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.

Things you must not do

Do not take Irbesartan Sandoz to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

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

This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

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

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.

SIDE EFFECTS

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- headache

- dizziness or light-headedness
- 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 (symptoms of an allergic reaction)
- aching muscles or aching joints (not caused by exercise), muscle pain or weakness
- 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
- yellowing of the skin and eyes, also called jaundice
- symptoms that may indicate high potassium levels in the blood, such as nausea, diarrhoea, muscle weakness, 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.

The above list includes serious side effects that may require medical attention. Serious side effects are not common.

If any of the following happen, stop taking this medicine and tell your doctor immediately or go to Accident and Emergency 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.

The above list includes serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Other side effects not listed above may also occur in some people.

AFTER TAKING IRBESARTAN SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Irbesartan Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask

your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Irbesartan Sandoz comes in three types of tablets:

Irbesartan Sandoz 75mg - white, oval biconvex film-coated tablets, marked "75" on one side and scored on the other side.

Irbesartan Sandoz 150mg - white, oval biconvex film-coated tablets, marked "150" on one side and scored on the other side.

Irbesartan Sandoz 300mg - white, oval biconvex film-coated tablets, marked "300" on one side and scored on the other side.

Available in packs of 30 tablets.

Ingredients

Active ingredients:

- Irbesartan Sandoz 75mg - 75mg
irbesartan
- Irbesartan Sandoz 150mg - 150mg
irbesartan
- Irbesartan Sandoz 300mg - 300mg
irbesartan

Inactive ingredients:

- microcrystalline cellulose
- lactose
- croscarmellose sodium
- colloidal anhydrous silica
- hypromellose
- magnesium stearate
- hydroxypropylcellulose
- macrogol 6000
- purified talc
- titanium dioxide

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

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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Australian Register Number(s)

75mg tablets: AUST R 167406 (blister packs)

150mg tablets: AUST R 167409 (blister packs)

300mg tablets: AUST R 167407 (blister packs)