

IRBESARTAN RBX

Irbesartan 75/150/300 mg Tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

Read this leaflet carefully before taking IRBESARTAN RBX. This leaflet answers some common questions about IRBESARTAN RBX. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. Do not throw this leaflet away. You may need to refer to it again later.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

Always follow the instructions that your doctor and pharmacist give you about IRBESARTAN RBX. If you have any concerns about taking IRBESARTAN RBX, ask your doctor or pharmacist.

WHAT IRBESARTAN RBX TABLET IS USED FOR

IRBESARTAN RBX 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 RBX. 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, taking the stairs instead of the lift, housework or gardening.

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

What IRBESARTAN RBX does and how it works

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

IRBESARTAN RBX slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Your doctor may have prescribed IRBESARTAN RBX for another use. If you want more information, ask your doctor.

BEFORE YOU TAKE IRBESARTAN RBX

When you must not take it

Do not take IRBESARTAN RBX 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. IRBESARTAN RBX should not be used during pregnancy.
- you are breast-feeding. It is not known if IRBESARTAN RBX passes into breast milk. Your doctor will decide whether to discontinue breast-feeding or to discontinue the medicine.
- you are allergic to IRBESARTAN RBX or to any of the ingredients listed under Product Description at the end of this leaflet.
- the packaging is torn or shows signs of tampering
- the expiry date 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 RBX, talk to your doctor.

IRBESARTAN RBX should not be given to children.

Before you start to take it

Tell your doctor if:

- you are or intend to become pregnant or plan to breast-feed
- you have recently had excessive vomiting or diarrhoea
- you suffer from any medical conditions, especially kidney or heart problems
- you are strictly restricting your salt intake
- you have high level of potassium in your blood (as identified by blood test from your doctor)
- you have Lapp lactase deficiency, galactose intolerance or glucose-galactose malabsorption (rare hereditary intolerances to particular sugars)
- you have had any allergies to any other medicine 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 RBX. Ask your doctor before you start taking any medicine if you are not sure.

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 medicines for high blood pressure
- fluid tablets or diuretics

- lithium or lithium-containing medicines
- potassium tablets or potassium-containing salt substitutes
- anti-inflammatory medicines (these are used to relieve pain, swelling and other symptoms of inflammation, including arthritis) and include nonsteroidal anti-inflammatory agents, called 'NSAIDs' and 'COX-2 inhibitors'.

Taking a combination of IRBESARTAN RBX and an anti-inflammatory medicine, alone or with a thiazide diuretic (fluid tablet) may damage your kidneys. It may also reduce the effect IRBESARTAN RBX has on reducing blood pressure.

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 RBX

The tablets should be taken regularly as directed by your doctor. The tablets should be swallowed with a glass of water.

Your doctor may also prescribe you other blood pressure lowering medicines along with IRBESARTAN RBX tablet.

How much to take

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

Depending on how your blood pressure responds, your daily dose of IRBESARTAN RBX may need to be increased. Most patients take either 150 mg or 300 mg each day.

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.

When to take it

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

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

How long to take it

IRBESARTAN RBX helps to control your high blood pressure, but it does not cure it. Therefore IRBESARTAN RBX must be taken every day. Continue taking IRBESARTAN RBX 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 the Poisons Information Centre (telephone 13 11 26 in Australia), if you or anyone else may have taken too much IRBESARTAN RBX. Do this even if there are no signs of discomfort or poisoning.

If you take too many IRBESARTAN RBX tablets you will probably feel lightheaded or dizzy.

WHILE YOU ARE USING IRBESARTAN RBX TABLETS

Things you must do

- If you become pregnant while taking IRBESARTAN RBX, tell your doctor immediately.
- Have your blood pressure checked when your doctor tells you to, to make sure IRBESARTAN RBX is working.
- If you are about to start on any new medicine, tell your doctor and pharmacist that you are taking IRBESARTAN RBX.
- Get up slowly when getting out of bed or standing up.
You may feel light-headed or dizzy while taking IRBESARTAN RBX, 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 (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking IRBESARTAN RBX.
- Make sure you drink enough water during exercise and hot weather when you are taking IRBESARTAN RBX, especially if you sweat a lot.
If you do not drink enough water while taking IRBESARTAN RBX, 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 RBX, 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 RBX tablets 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 RBX affects you.
As with many other medicines used to treat high blood pressure, IRBESARTAN RBX may cause dizziness or light-headedness in some people.
Make sure you know how you react to IRBESARTAN RBX 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

IRBESARTAN RBX 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 or pharmacist as soon as possible if you do not feel well while you are taking IRBESARTAN RBX.

Do not be alarmed by the following list of side effects. As many of them are uncommon you may not experience them.

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

- dizziness or light-headedness (vertigo), especially upon rising from a sitting or lying position
- unusual tiredness or weakness, fatigue
- flu
- chest pain
- diarrhoea or constipation
- weight gain
- indigestion/heart burn
- abdominal pain, bloating, wind
- anxiety/nervousness or breathlessness
- fast or irregular heart beat
- infections of respiratory tract
- visual disturbances
- dry mouth
- flushing
- fainting
- nose bleeds
- sexual dysfunction, trouble urinating
- excessive sweating
- pain, stiffness, numbness, difficulty in sleep, depression, emotional disturbances
- sensation of tingling, pricking, itching or numbness
- cramps, weakness, shaking or tremors, coordination problem

They are generally mild and do not normally require treatment to be interrupted.

Tell your doctor immediately if you notice any of the following:

- persistent muscle weakness or pain
- buzzing, ringing or other persistent noise in the ears, hearing problems
- symptoms of anaemia such as tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- yellowing of the skin and/or eyes, also called jaundice, other liver disease, elevated liver enzymes
- fainting, shortness of breath or chest pain that may spread to neck and shoulders
- painful, swollen joints, not caused by exercise but by the presence of uric acid crystals (gout)
- 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 very high potassium levels in the blood such as nausea, diarrhoea, muscle weakness and change in heart rhythm

These are serious side effects. You may need medical attention.

If any of the following happen, stop taking IRBESARTAN RBX and tell your doctor immediately or go to Accident and Emergency Department at your nearest hospital -

- 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.

These are very serious side effects. If you have them you have had a serious allergic reaction to IRBESARTAN RBX. 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 for their advice.

AFTER USING IT

Storage

Keep your IRBESARTAN RBX 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.

Keep IRBESARTAN RBX tablets in a cool dry place where the temperature stays below 25°C. Do not store IRBESARTAN RBX or any other medicine in the bathroom or near a sink. 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 all medicines out of the reach of children.

A locked cupboard at least one-and-a-half metres (5 feet) above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking IRBESARTAN RBX 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 RBX tablets are white to off-white, oval-shaped tablets with 'I3' (75 mg), 'I4' (150 mg) or 'I5' (300 mg) marked on one side.

They are available in blister packs of 30 tablets, each containing the active ingredient irbesartan.

Inactive ingredients:

- lactose,
- microcrystalline cellulose,
- croscarmellose sodium,
- hypromellose,
- colloidal anhydrous silica,
- magnesium stearate,
- titanium dioxide,
- Macrogol 4000.

IRBESARTAN RBX does not contain sucrose, glucose, gluten, tartrazine or any other azo dyes.

Australian Register Numbers:

AUST R 190475 (75 mg),
190478 (150 mg) &
190482 (300 mg).

Sponsor

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Australia

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