

IRBESARTAN/HCTZ RBX tablets

Irbesartan and Hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking IRBESARTAN/HCTZ RBX tablets. This leaflet answers some common questions about IRBESARTAN/HCTZ RBX tablets. 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/HCTZ RBX tablets.

If you have any concerns about taking IRBESARTAN/HCTZ RBX tablets, ask your doctor or pharmacist.

What IRBESARTAN/HCTZ RBX tablets are used for

IRBESARTAN/HCTZ RBX tablets contain two medicines, irbesartan and hydrochlorothiazide. Both these medicines are in the tablets your doctor has prescribed for you.

IRBESARTAN/HCTZ RBX tablets lower 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/HCTZ RBX tablets. 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.

What IRBESARTAN/HCTZ RBX does and how it works

IRBESARTAN/HCTZ RBX contains irbesartan and hydrochlorothiazide. Both medicines reduce blood pressure in different ways. Irbesartan 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 blocks angiotensin-II and therefore relaxes your blood vessels. This helps to lower your blood pressure.

Hydrochlorothiazide belongs to the class of medicines known as diuretics. Diuretics cause an increase in the volume of urine. They also help with lowering blood pressure particularly when combined with other blood pressure reducing medicines. Your doctor may have prescribed IRBESARTAN/HCTZ RBX tablets for another use. If you want more information, ask your doctor.

When you must not take IRBESARTAN/HCTZ RBX tablets

Do not take IRBESARTAN/HCTZ RBX tablets 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.

- you are breast-feeding. It is not known if IRBESARTAN/HCTZ RBX passes into breast milk. Your doctor will decide whether to discontinue breast-feeding or to discontinue the medicine.
- you are allergic to irbesartan or hydrochlorothiazide or to sulfonamide derived medicines, or to any of the ingredients listed under Product Description at the end of this leaflet.
- you are taking a medicine containing aliskiren and either have diabetes or moderate to severe kidney impairment.
- you are not producing urine.
- 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/HCTZ RBX tablets, talk to your doctor.

IRBESARTAN/HCTZ RBX tablets should not be given to children.

Before you start to take IRBESARTAN/HCTZ RBX tablets

Tell your doctor if:

- you are or intend to become pregnant or plan to breast-feed. IRBESARTAN/HCTZ RBX tablets should not be used during pregnancy or while breast-feeding
- you have recently had excessive vomiting or diarrhoea or think you are dehydrated
- you suffer from any medical conditions especially:
 - kidney problems, or have had a kidney transplant or dialysis
 - heart problems
 - liver problems, or have had

liver problems in the past

- diabetes
- gout or have had gout in the past
- lupus erythematosus
- high or low levels of potassium or sodium or other electrolytes in your blood
- primary aldosteronism
- you are strictly restricting your salt intake
- you are lactose intolerant or have had any allergies to any other medicine or any other substances, such as foods, preservatives or dyes
- have had a sympathectomy
- you have been taking diuretics
- you have a history of allergy or asthma

Be sure you tell your doctor about any of these things before you take any IRBESARTAN/HCTZ RBX tablets.

Taking IRBESARTAN/HCTZ RBX tablets with other medicines

Tell your doctor if you are taking 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 (for example Lithicarb®)
- potassium tablets (for example Span-K, Slow-K, Mag-K)
- potassium-containing salt substitutes (for example Pressor-K)
- anti-inflammatory medicines (these are used to relieve pain, swelling and other symptoms of inflammation, including arthritis) and include nonsteroidal anti-inflammatory agents – NSAIDS (for example

Voltaren, Indocid, ibuprofen)

and COX-2 inhibitors (for example Celebrex)

Taking a combination of IRBESARTAN/HCTZ 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/HCTZ RBX has on reducing blood pressure.

- a medicine containing aliskiren. Taking IRBESARTAN/HCTZ RBX with aliskiren may affect your blood pressure, electrolyte balance and your kidney function
- alcoholic drinks
- sleeping tablets
- strong pain killing medicines (for example narcotics such as codeine or morphine)
- medicines for diabetes (oral tablets or capsules or insulins)
- calcium supplements, medicines containing calcium or calcium sparing drugs (for example Vitamin D therapy)
- medicines for gout
- powder or granules used to help reduce cholesterol (Questran Lite or Colestid Granules)
- heart medicines such as digoxin or antiarrhythmic medicines (for example Sotacor®)
- corticosteroid medicines such as prednisone, cortisone or ACTH
- medicines used to treat cancer (cytotoxic medicines)
- amantadine (Symmetrel®), a medicine used to treat Parkinson's disease or to prevent influenza
- anticholinergic medicines, these can be used to treat Parkinson's disease, to relieve stomach cramps or spasms or used to prevent travel sickness
- carbamazepine, an anticonvulsant medication (such as Tegretol®)
- medicines used during surgery

- medicines used in an emergency situation such as adrenaline

Your doctor will decide whether your treatment needs to be altered or whether you should have check ups more frequently.

HOW to take IRBESARTAN/HCTZ RBX tablets

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

How much to take:

IRBESARTAN/HCTZ RBX tablets will usually be prescribed by your doctor if previous treatment does not produce a sufficient drop in your blood pressure. Your doctor will tell you how to switch from your previous treatment to IRBESARTAN/HCTZ RBX tablets.

The usual dose of IRBESARTAN/HCTZ RBX is one tablet a day. The full blood pressure lowering effect should be reached 4-6 weeks after beginning treatment. If your blood pressure is not satisfactorily reduced with IRBESARTAN/HCTZ RBX tablets, your doctor may prescribe another medicine to be taken with IRBESARTAN/HCTZ RBX.

When to take it:

You should always take your daily dose of IRBESARTAN/HCTZ RBX at about the same time each day. Taking your IRBESARTAN/HCTZ RBX tablets at the same time each day will have the best effect. It does not matter whether you take IRBESARTAN/HCTZ RBX tablets before or after food.

How long to take it:

IRBESARTAN/HCTZ RBX tablets help to control your high blood pressure, but do not cure it.

Therefore IRBESARTAN/HCTZ RBX tablets must be taken every day. Continue taking IRBESARTAN/HCTZ RBX tablets until your doctor tells you to stop.

If you miss a dose:

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 makeup for the missed dose.

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

If you take too much IRBESARTAN/HCTZ RBX (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone: 13 11 26) or go to the Accident and Emergency Department at your nearest hospital, if you or anyone else may have taken too much IRBESARTAN/HCTZ RBX.

Do this even if there are no signs of discomfort or poisoning.

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

While you are taking IRBESARTAN/HCTZ RBX tablets

Things you must do:

- If you become pregnant while taking IRBESARTAN/HCTZ RBX tell your doctor immediately.
- Have your blood pressure checked when your doctor tells you to, to make sure

IRBESARTAN/HCTZ RBX tablets are working.

- If you are about to start on any new medicine, tell your doctor and pharmacist that you are taking IRBESARTAN/HCTZ RBX tablets.
- Get up slowly when getting out of bed or standing up. You may feel light-headed or dizzy while taking IRBESARTAN/HCTZ RBX tablets. 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. If you get dizzy or lightheaded, talk to your doctor.
- If you plan to have surgery or other treatment (even at the dentist) that needs an anaesthetic, make sure that you tell your doctor or dentist that you are taking IRBESARTAN/HCTZ RBX tablets
- Make sure you drink enough water during exercise and hot weather when you are taking IRBESARTAN/HCTZ RBX tablets, especially if you sweat a lot. If you do not drink enough water while taking IRBESARTAN/HCTZ RBX tablets, 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/HCTZ RBX tablets, tell your doctor. This can also mean that you are losing too much water and your blood pressure may become too low.

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.

Things you must not do:

- Do not give IRBESARTAN/HCTZ RBX 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/HCTZ RBX affect you. As with many other medicines used to treat high blood pressure, IRBESARTAN/HCTZ RBX tablets may cause dizziness or light-headedness in some people. Make sure you know how you react to IRBESARTAN/HCTZ 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.
- The hydrochlorothiazide contained in this medicine could produce a positive analytical result in an antidoping test.

Side Effects

IRBESARTAN/HCTZ RBX tablets help 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/HCTZ RBX tablets.

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

- headache
- dizziness or light-headedness (vertigo)
- unusual tiredness or weakness, fatigue
- pain in the stomach or gut; nausea and/or vomiting
- sexual problems

These 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
- aching muscles or aching joints, not caused by exercise
- muscle pain, weakness or paralysis of muscles
- buzzing, ringing or other persistent noise in the ears
- changes in heart rhythm
- you are not urinating (passing water) as much as normal
- numbness or tingling in fingers or toes
- painful, swollen joints which may be symptoms of gout
- fainting
- yellowing of the skin and/or eyes, also known as jaundice
- symptoms that may occur if you have developed diabetes, such as excessive thirst, passing greatly increased amounts of urine, increased appetite with weight loss, feeling tired, drowsy, weak, depressed, irritable and generally unwell
- 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 and changes in heart rhythm
- disturbances in your vision (such as blurred vision and seeing haloes around lights) and eye pain

These are serious side effects. Skin rash and itchiness may be symptoms of an allergic reaction. You may need medical attention. These side effects are not common.

If any of the following happen, stop taking IRBESARTAN/HCTZ RBX tablets and tell your doctor immediately or go to Accident & Emergency at your nearest hospital:

- swelling of the face, lips, tongue or throat, which may cause difficulty in swallowing/ breathing or wheezing, or severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash. These may be signs of a serious allergic reaction to IRBESARTAN/HCTZ RBX tablets
- symptoms that may indicate liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine.

These are very serious side effects. 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 IRBESARTAN/HCTZ RBX tablets

Storage:

Keep your IRBESARTAN/HCTZ RBX tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they will not keep well.

Keep IRBESARTAN/HCTZ RBX tablets in a cool, dry place where the temperature stays below 25°C. Do not store IRBESARTAN/HCTZ RBX

tablets or any other medicine in the bathroom near a sink. Do not leave them near a radiator, in a car on a hot day 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/HCTZ 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/HCTZ RBX tablets are coloured, oval-shaped tablets marked on one side and plain on the other.

Active Ingredients

- **IRBESARTAN/HCTZ RBX tablets 150/12.5** - contain irbesartan 150 mg and hydrochlorothiazide 12.5 mg per tablet. They are pink/red coloured with 'IH 1' on one side.
- **IRBESARTAN/HCTZ RBX tablets 300/12.5** - contain irbesartan 300 mg and hydrochlorothiazide 12.5 mg per tablet. They are yellow coloured with 'IH 3' on one side.
- **IRBESARTAN/HCTZ RBX tablets 300/25** - contain irbesartan 300 mg and hydrochlorothiazide 25 mg per tablet. They are pink/red coloured with 'IH 2' on one side.

Other Ingredients

The inactive ingredients in IRBESARTAN/HCTZ RBX tablets are:

- Lactose
- Microcrystalline cellulose
- Croscarmellose sodium
- Hypromellose
- Colloidal anhydrous silica
- Magnesium stearate
- Titanium dioxide
- Macrogol 400
- Macrogol 4000
- Purified talc
- Iron oxide red (150/12.5 & 300/25 strengths only)
- Iron oxide black (150/12.5 & 300/25 strengths only)
- Iron oxide yellow (300/12.5 strength only).

IRBESARTAN/HCTZ RBX does not contain sucrose, gluten, tartrazine or any azo dyes.

Australian Register Numbers:

AUST R 190470 (150/12.5 strength),
190460 (300/12.5 strength) &
190466 (300/25 strength).

Sponsor

Ranbaxy Australia Pty Ltd.

9-13 Waterloo Road
Macquarie Park NSW 2113

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