

IRBESARTAN-DRLA Tablets

Irbesartan

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking IRBESARTAN-DRLA. This leaflet answers some common questions about IRBESARTAN-DRLA. 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.

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

What is IRBESARTAN-DRLA

IRBESARTAN-DRLA is a trade name (manufacturer's name) for the medicine, irbesartan. This medicine is in the tablets your doctor has prescribed for you.

What IRBESARTAN-DRLA is used for
IRBESARTAN-DRLA 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-DRLA. 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, etc...

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

What IRBESARTAN-DRLA does and how it works

IRBESARTAN-DRLA 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-DRLA blocks angiotensin-II and therefore relaxes your blood vessels. This helps to lower your blood pressure. IRBESARTAN-DRLA slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

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

When you must not take IRBESARTAN-DRLA

Do not take IRBESARTAN-DRLA 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-DRLA passes into breast milk, therefore it is not recommended to be taken while you are breast-feeding.
- you are allergic to irbesartan 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-DRLA, talk to your doctor.

IRBESARTAN-DRLA should not be given to children.

Before you start to take IRBESARTAN-DRLA

Tell your doctor if:

- you are or intend to become pregnant or plan to breast-feed
IRBESARTAN-DRLA should not be used during pregnancy or while breast-feeding
- you have recently had excessive vomiting or diarrhoea
- you suffer from any medical conditions especially - kidney or heart problems, liver problems, or have had liver problems in the past
- 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.

Be sure you tell your doctor about any of these things before you take any IRBESARTAN-DRLA.

Taking IRBESARTAN-DRLA with 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 tablets 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) and COX-2 inhibitors (for example Celebrex).

Taking a combination of Irbesartan-DRLA with a thiazide diuretic (fluid tablet) and an anti-inflammatory medicine may damage your kidneys.

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-DRLA

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

How much to take:

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

Usually patients start with one 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-DRLA should be reached about 4-6 weeks after starting treatment.

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

In patients with high blood pressure and type 2 diabetes, 300mg once daily is the preferred maintenance dose for the treatment of associated kidney disease.

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-DRLA at about the same time each day. Taking your IRBESARTAN-DRLA tablets at the same time each day will have the best effect.

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

How long to take it:

IRBESARTAN-DRLA helps to control your high blood pressure, but it does not cure it. Therefore IRBESARTAN-DRLA must be taken every day. Continue taking IRBESARTAN-DRLA 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 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 IRBESARTAN-DRLA (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) or go to the Accident and Emergency Department at your nearest hospital, if you or anyone else may have taken too much IRBESARTAN-DRLA. Do this even if there are no signs of discomfort or poisoning.

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

While you are using Irbesartan-DRLA

Things you must do:

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

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
- 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
- aching muscles or aching joints, not caused by exercise
- muscle pain
- buzzing, ringing or other persistent noise in the ears
- 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 and change in heart rhythm

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-DRLA 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 serious side effects. If you have them you have had a serious allergic reaction to IRBESARTAN-DRLA. 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-DRLA

Storage:

Keep your IRBESARTAN-DRLA tablets in the original packaging until it is time to take them. If you take the tablets out of the original packaging they may not keep well.

Keep IRBESARTAN-DRLA tablets in a cool dry place where the temperature stays below 25°C. Do not store IRBESARTAN-DRLA 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 above the ground is a good place to store medicines.

Disposal:

If your doctor tells you to stop taking IRBESARTAN-DRLA 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-DRLA 75 mg tablets - White to off-white, oval shaped, film coated tablets debossed with 'IRB' on one side and '75' on other side.

Pack & pack sizes:

Blister Pack: 30's, 14's, 98's, 56's, 3's, 5's, 7's and 28's tablets.

Bottle pack: 30's, 7's, 90's and 14's tablets.

AUST R 190487

AUST R 190500

IRBESARTAN-DRLA 150 mg tablets - White to off-white, oval shaped, film coated tablets debossed with 'IRB' on one side and '150' on other side.

Pack & Pack sizes:

Blister Pack: 30's, 14's, 98's, 56's, 3's, 5's, 7's and 28's tablets.

Bottle pack: 30's, 7's, 90's and 14's tablets.

AUST R 190520

AUST R 190489

IRBESARTAN-DRLA 300 mg tablets - White to off-white, oval shaped, film coated tablets debossed with 'IRB' on one side and '300' on other side.

Pack & Pack sizes:

Blister Pack: 30's, 14's, 98's, 56's, 3's, 5's, 7's and 28's tablets.

Bottle pack: 30's, 7's, 90's and 14's tablets.

AUST R 190515

AUST R 190488

Active ingredients

- IRBESARTAN-DRLA 75 mg tablets - 75 mg irbesartan per tablet.
- IRBESARTAN-DRLA 150 mg tablets - 150 mg irbesartan per tablet.
- IRBESARTAN-DRLA 300 mg tablets - 300 mg irbesartan per tablet.

Other Ingredients

IRBESARTAN-DRLA tablets also contain

- lactose,
- cellulose- microcrystalline,
- crospovidone, povidone,
- silica- colloidal anhydrous,
- magnesium stearate,
- hypromellose,
- titanium dioxide and
- macrogol 4000.

How current is this information and where can I find out more?

This leaflet was produced based on information known by Dr. Reddy's Laboratories (Australia) Pty Ltd in October 2011. You need to consult your doctor regularly as your doctor has access to information on any changes which may affect you.

Who makes IRBESARTAN-DRLA?

IRBESARTAN-DRLA is made available by **Dr. Reddy's Laboratories (Australia) Pty Ltd**
Level 1, 181 Bay Street
Brighton VIC 3186
Australia

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