

CRUZOR TABLET

Irbesartan (150mg, 300mg)

What is in this leaflet

1. What Cruzor Tablet is used for
2. How Cruzor Tablet works
3. Before you use Cruzor Tablet
4. How to use Cruzor Tablet
5. While you are using Cruzor Tablet
6. Side effects
7. Storage and disposal of Cruzor Tablet
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Cruzor Tablet is used for

Cruzor tablet is used to treat high blood pressure (essential hypertension) and to protect the kidney in patients with high blood pressure, type 2 diabetes with laboratory evidence of impaired kidney function.

How Cruzor Tablet works

Cruzor tablet contains Irbesartan as the active ingredient.

Irbesartan belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels causing them to tighten. This resulting in an increase in blood pressure. Irbesartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower.

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

Before you use Cruzor Tablet

-When you must not use it

Do not take Cruzor tablet if you: -

- have an allergy to Irbesartan or any of the ingredients listed at the end of this leaflet.
- are more than 3 months pregnant. (It is also better to avoid taking Irbesartan in early pregnancy)
- are breast-feeding.

If you are not sure whether you should start taking this medicine, do consult your doctor.

-Before you start to use it

Cruzor Tablet contains lactose. If you have been told by your doctor that you have lactose intolerance, consult your doctor before taking this medicine.

-Taking other medicines

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

Some medicines and Cruzor tablet may interfere with each other. These include:

- Diuretics (medication that increase production of urine) and other antihypertensive (blood pressure lowering) medicines.
- Potassium supplements and potassium-sparing diuretics.
- Non-steroidal anti-inflammatory drugs (medicines used to treat pain and fever).
- Lithium
- Mifepristone (abortion medicine).
- Amiodarone (an antiarrhythmic medication used to treat and prevent a number of types of irregular heartbeats)

If you are not sure, please talk to your doctor or pharmacist before taking Cruzor Tablet.

How to use Cruzor Tablet

-How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information stated in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Cruzor Tablet can be taken with or without food.

Patients with high blood pressure

The usual dose is 150 mg once a day. The dose may later be increased to 300 mg once daily depending on your blood pressure condition.

Patients with high blood pressure and type 2 diabetes with kidney disease

Initiation dose is 150mg once daily. 300 mg once daily is the preferred maintenance dose for the treatment associated with kidney disease.

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those on haemodialysis, or those over the age of 75 years old.

Cruzor Tablet is not breakable. If lower starting dose is considered necessary, the 150 mg tablet not being breakable, alternative therapy should be considered.

-When to use it

Take as directed by your doctor or pharmacist.

-How long to use it

Continue taking Cruzor Tablet as per prescribed by doctor.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget

to take your medicine.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and please skip the missed dose.

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

-If you take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken this medicine excessively. Even if there are no signs of discomfort or poisoning, please seek medical help. You may need urgent medical attention.

While you are using Cruzor Tablet

-Things you must do

Take your medicine exactly as your doctor has told you.

Notify your doctors, dentists and pharmacists treating you that you are taking Cruzor Tablet.

Tell your doctor immediately if you are pregnant while taking this medication.

-Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give or share Cruzor Tablet with anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Cruzor Tablet before you become

pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Cruzor Tablet.

Cruzor Tablet is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if continue taking after the third month of your pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Cruzor Tablet is not recommended for mothers who are breast-feeding. Your doctor may choose another treatment for you if you wish to continue breast-feeding, especially if your baby is new-born, or was born premature.

Driving and using machines

Be careful driving or operating machinery until you know how Cruzor Tablet affects you.

Side effects

Like all medicines, Cruzor Tablet can cause several side effects, although not everybody gets them. Some of these effects may be serious and may require medical attention.

Tell your doctor or pharmacist if you notice any of the following side effects:

- increased blood potassium levels, raised levels of an enzyme that measures the muscle and heart function (creatinase enzyme);
- hypersensitivity reactions such as swelling, rash or hives, inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis).
- headache, dizziness, hypotension, dizziness when

getting up from a lying or sitting position.

- experiencing ringing or other noises in one or both of your ears)
- heart rate increased.
- cough
- nausea, vomiting, diarrhoea, indigestion/heartburn, taste disturbance.
- hepatitis, abnormal liver function, jaundice.
- low blood platelet count.
- pain in joints and muscles, muscle cramps.
- impaired kidney function.
- sexual dysfunction.
- fatigue, chest pain.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my (Public Reporting Side Effects to medicines (ConSERF)/ Vaccine (AEFI)).

Storage and Disposal of Cruzor Tablet

-Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not take the tablets beyond expiry date stated on the pack and blisters.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Cruzor Tablet 150mg

12.5 mm length, white to off-white, oval-shaped film-coated tablet with Pharmaniaga icon on one side and plain on the other side.

Cruzor Tablet 300mg

15.5 mm length, white to off-white, oval-shaped film-coated tablet with Pharmaniaga icon on one side and plain on the other side.

-Ingredients

-Active ingredient:

Cruzor Tablet 150mg

Each tablet contains Irbesartan 150mg.

Cruzor Tablet 300mg

Each tablet contains Irbesartan 300mg.

-Inactive ingredient:

Lactose monohydrate,
Hydroxypropyl methylcellulose,
Croscarmellose sodium,
Microcrystalline cellulose 102,
Croscarmellose sodium, Colloidal
silicone dioxide, Magnesium
stearate, Opadry White and
Purified Water.

-MAL number

Cruzor Tablet 150mg

MAL21116025AZ

Cruzor Tablet 300mg

MAL21116024AZ

Manufacturer:

Pharmaniaga Manufacturing
Berhad (60016-D),
11A, Jalan P/1, Kawasan
Perusahaan Bangi, 43650 Bandar
Baru Bangi, Selangor Darul Ehsan,
Malaysia.

Product Registration Holder:

Pharmaniaga Manufacturing
Berhad (60016-D),
11A, Jalan P/1, Kawasan
Perusahaan Bangi, 43650 Bandar
Baru Bangi, Selangor Darul Ehsan,
Malaysia.

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