

DYNACARD–150/300(Irbesartan Tablet 150/300 mg)

Irbesartan (150mg, 300mg)

What is in this leaflet

1. What Dynacard Tablets is used for
2. How Dynacard Tablets works
3. Before you use Dynacard Tablets
4. How to use Dynacard Tablets
5. While you are using it
6. Side effects
7. Storage and Disposal of Dynacard Tablets
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Dynacard Tablets is used for

Dynacard Tablets is used

- to treat high blood pressure (hypertension)
- to protect the kidney in patients with high blood pressure, type 2 diabetes and laboratory evidence of impaired kidney function

How Dynacard Tablets works

Dynacard Tablets 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 results in an increase in blood pressure. Dynacard Tablets prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower. Dynacard Tablets slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Before you use Dynacard Tablets

- When you must not use it

Do not take Dynacard Tablets

- If you are allergic (hypersensitive) to Irbesartan or any of the other excipients of Dynacard Tablets.
- if you are **more than 3 months pregnant**. (It is also better to avoid Dynacard Tablets in early pregnancy – see pregnancy section)

Dynacard Tablets should not be given to children and adolescents.

- Before you start use it

Take special care with Dynacard Tablets

Tell your doctor if any of the following apply to you:

- if you get **excessive vomiting or diarrhoea**
- if you suffer from **kidney problems**
- if you suffer from **heart problems**
- if you receive Dynacard Tablets for **diabetic kidney disease**. In this case your doctor may perform regular blood tests, especially for measuring blood potassium levels in case of poor kidney function.

You must tell your doctor if you think you are (or might become) pregnant. Dynacard Tablets is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

How to use Dynacard Tablets

- How much to use

• 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 blood pressure response.

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

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

The blood pressure lowering effect should be reached 1-2 weeks after beginning treatment.

Always take Dynacard Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- When to use it

Dynacard Tablets is for **oral use**. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take Dynacard Tablets with or without food. Try to take your daily dose at about the same time each day. It is important that you continue to take Dynacard Tablets until your doctor tells you otherwise.

- How long to use it

It is important that you continue to take Dynacard Tablets until your doctor tells you otherwise.

- If you forget to use it

If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

- If you use too much (overdose)

If you accidentally take too many tablets, contact your doctor immediately.

While you are using it

- Things you must do

You may need to have blood checks if you take:

- potassium supplements
- salt substitutes containing potassium
- potassium-sparing medicines (such as certain diuretics)
- medicines containing lithium

If you take certain painkillers, called non-steroidal anti-inflammatory drugs, the effect of Irbesartan may be reduced.

Taking Dynacard Tablets with food and drink

Dynacard Tablets can be taken with or without food.

- Things you must not do

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Dynacard Tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Dynacard Tablets. Dynacard Tablets 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 used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Dynacard Tablets is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

- Things to be careful of

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. Dynacard Tablets is unlikely to affect your ability to drive or use machines. However, occasionally dizziness or weariness may occur during treatment of high blood pressure. If you experience these, talk to your doctor before attempting to drive or use machines.

Important information about some of the ingredients of Dynacard Tablets

Dynacard Tablets contains lactose. If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicinal product.

Side effects

Like all medicines, Dynacard Tablets can cause side effects, although not

everybody gets them. Some of these effects may be serious and may require medical attention.

As with similar medicines, rare cases of allergic skin reactions (rash, urticaria), as well as localized swelling of the face, lips and/or tongue have been reported in patients taking Irbesartan. If you get any of these symptoms or get short of breath, **stop taking Dynacard Tablets and contact your doctor immediately.**

Side effects:

Very common: if you suffer from high blood pressure and type 2 diabetes with kidney disease, blood tests may show an increased level of potassium.

Common: dizziness, feeling sick/vomiting, fatigue and blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatine kinase enzyme). In patients with high blood pressure and type 2 diabetes with kidney disease, dizziness when getting up from a lying or sitting position, low blood pressure when getting up from a lying or sitting position, pain in joints or muscles and decreased levels of a protein in the red blood cells (haemoglobin) were also reported.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Dynacard Tablets

- Storage

Keep out of the reach of children.

Do not use Dynacard Tablets after the expiry date, which is stated on the carton and on the blister after EXP.

Store below 30°C.

- Disposal

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

Product Description

- What it looks like

Dynacard-150 are supplied as white to off white, biconvex, oval shaped, film coated tablets with 'U22' engraved on one side and plain on the other side.

Dynacard-300 are supplied as white to off white, biconvex, oval shaped, film coated tablets with 'U23' engraved on one side and plain on the other side.

- Ingredients

- Active ingredient

The active substance is Irbesartan.

- Inactive ingredients

Tablet core: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hypromellose 2910, silica colloidal anhydrous, magnesium stearate.

Tablet coating: Opadry 32F38977 White (lactose monohydrate, hypromellose, titanium dioxide (E 171), macrogol 3000)

- MAL number(s):

Manufacturer

USV Private Limited
H-13,16,16A,17,18,19,20,21,E-22,
O.I.D.C., Mahatma Gandhi Udyog Nagar,
Dabhel, Daman – 396210, India.

Product Registration Holder:

KCK Pharmaceutical Industries Sdn Bhd
Plot 61, Bayan Lepas Industrial Park
Phase 4, Lintang Bayan Lepas 1,
11900 Bayan Lepas, Pulau Pinang.

Importer:

KCK Pharmaceutical Industries Sdn Bhd
Wisma Fuji, Plot 61,
Bayan Lepas Industrial Park Phase 4,
11900 Bayan Lepas, Pulau Pinang.

Date of revision

21 December 2018