

NEBICARD TABLET

Consumer Medication Information Leaflet (RiMUP)

Nebivolol hydrochloride Tablets 5mg

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What Nebicard is used for

Nebicard is indicated in the treatment of essential hypertension.

How Nebicard works

This medicine belongs to a group of medicines called beta-blockers. Nebivolol can be used to treat high blood pressure. It works by blocking the transmission of messages to the beta receptors in the heart which slows down the activity of the heart. It also relaxes the blood vessels and reduces the resistance that the heart has to pump against.

Before you use Nebicard

- When you must not use it
Do not use Nebicard if you are:
Allergic (hypersensitive) to Nebivolol or any of the other ingredients of Nebicard.
If you have one or more of the following disorders:

- have liver problems
- have acute heart failure or cardiogenic shock, a serious heart condition causing low blood pressure
- have a history of slow heart rate or uneven heart beating
- have certain other heart conditions
- have asthma or other lung disease with tightening of the airways
- have untreated phaeochromocytoma, a rare tumour of the adrenal gland
- have metabolic acidosis, where there is too much acid in the blood

- have hypotension, low blood pressure
- have a severe blood vessel disorder causing poor circulation in the arms and legs

Do not take Nebicard if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Nebicard if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Inform your doctor if you have or develop one of the following problems:

- Abnormally slow heartbeat
- A type of chest pain due to spontaneously occurring heart cramp called Prinzmetal angina
- Untreated chronic heart failure
- 1st degree heart block (a kind of light heart conduction disorder that affects heart rhythm)
- Poor circulation in the arms or legs, e.g. Raynaud's disease or syndrome, cramp-like pains when walking
- Prolonged breathing problems
- Diabetes: This medicine has no effect on blood sugar, but it could conceal the warning signs of a low sugar level (e.g. palpitations, fast heartbeat).
- Overactive thyroid gland: This medicine may mask the signs of an abnormally fast heart rate due to this condition
- Psoriasis (a skin disease - scaly pink patches) or if you have ever had psoriasis
- If you have to have surgery, always inform your anesthetist that you are on Nebicard before being anaesthetized.

- 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 Nebicard may interfere with each other. These include:

- Those used to treat irregular or abnormal heartbeat (eg. quinidine,

flecainide, disopyramide, lignocaine, mexiletine, amiodarone)

- Calcium channel blockers for high blood pressure or heart problems (eg. verapamil, diltiazem)
- Insulin and tablets used to treat diabetes
- Tricyclic antidepressants, barbiturates and phenothiazines
- Anesthetics may attenuate reflex tachycardia (a rapid heart rate) and increase the risk of hypotension.
- Those used to treat excessive stomach acid (e.g. cimetidine).
- Combining nebivolol with nicardipine slightly increased the plasma levels of both drugs

How to use Nebicard

- How much to use

The dose is one tablet daily, preferably at the same time of the day.

Patients with kidney insufficiency: In patients with kidney insufficiency, the recommended starting dose is 2.5 mg daily. If needed, the daily dose may be increased to 5 mg.

Patients with liver insufficiency:

Data in patients with hepatic insufficiency or impaired liver function are limited. Therefore the use of Nebicard in these patients is contraindicated.

Elderly: In patients over 65 years, the recommended starting dose is 2.5 mg daily. If needed, the daily dose may be increased to 5 mg.

- When to use it

Tablets may be taken with meals. Swallow the tablets whole with a full glass of water.
Do not crush or chew the tablets

- How long to use it

Continue taking Nebicard for as long as your doctor recommends

- If you forget to use it

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

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- *If you use 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 too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- *Things you must do*
Take your medicine exactly as your doctor has told you.
Tell all the doctors, dentists and pharmacists treating you that you are taking Nebicard.
Tell your doctor immediately if you become 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 Nebicard to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*
Driving and using machines
This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Nebicard can cause side effects, although not everybody gets them.
Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

- Most frequent adverse events are headache, dizziness, tiredness, tingling or “pins and needles” (paresthesia), diarrhoea, constipation, nausea, shortness of breath or difficulty breathing (dyspnea) and oedema (fluid retention).
- Slow heart beat (Bradycardia), chest pain or changes in heart

rate, a kind of light heart conduction disorder that affects heart rhythm (slowed AV-conduction /AV- block), hypotension, heart failure, impaired vision, sexual problems, abnormal thinking or depression, nightmares, digestive difficulties(dyspepsia), flatulence, vomiting, breathlessness such as in asthma, due to sudden cramps in the muscles around the airways (bronchospasm), rash.

- Other are: hallucinations, psychoses, confusion, coldness or numbness in the hands or feet, excessively reduced blood flow in response to cold or emotional stress, causing discoloration of the fingers, toes, and occasionally other areas (Raynaud’s phenomenon), dry eyes.

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 Nebicard

- *Storage*
Store below 30°C. Protect from moisture.

- *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*
White to off-white, round, biconvex, uncoated tablets, with cross break line on one side and plain on other side.

- *Ingredients*
- Active ingredient(s)
Nebivolol Hydrochloride

- Inactive ingredients

Lactose Monohydrate
Maize Starch
Croscarmellose Sodium
Hypromellose
Cellulose,
Microcrystalline
Colloidal Silicon Dioxide
Magnesium Stearate

- *MAL number:*
MAL10033185A

Manufacturer
TORRENT PHARMACEUTICALS LTD.
Indrad 382 721, District: Mehsana INDIA

Product Registration Holder
Laboratories Torrent (Malaysia) Sdn Bhd.,
Suite E-08-08 Plaza Mont Kiara,
No. 2 Jalan Kiara Mont Kiara,
50480 Kuala Lumpur Malaysia.

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28/08/2014