PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

NEBILET 5 mg tablets

Nebivolol (as nebivolol hydrochloride)

Contains sugar (141,75 mg lactose monohydrate)

Read all of this leaflet carefully before you start taking NEBILET 5 mg.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- NEBILET 5 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What NEBILET 5 mg is and what it is used for
2. What you need to know before you take NEBILET 5 mg
3. How to take NEBILET 5 mg
4. Possible side effects
5. How to store NEBILET 5 mg
6. Contents of the pack and other information.

1. What NEBILET 5 mg is and what it is used for

NEBILET 5 mg belongs to a group of medicines known as selective beta blocking agents that act selectively on the cardiovascular system. These medicines act by lowering blood pressure, preventing increased heart rate, and controlling heart pumping strength. It also exerts a dilating action on blood vessels, which contributes as well to lower blood pressure.

NEBILET 5 mg is used:

- To treat high blood pressure (hypertension).
- In the treatment of stable mild to moderate chronic heart failure in addition to standard therapies in elderly patients ≥ 70 years.

2. What you need to know before you take NEBILET 5 mg

Do not take NEBILET 5 mg if:

- You are hypersensitive (allergic) to nebivolol or any of the other ingredients of NEBILET 5 mg (listed in section 6).
- You have impaired liver functioning.
- You are pregnant or breastfeeding.
- You have low blood pressure.
- You have a very slow heartbeat (less than 60 beats per minute).
- You have certain other serious heart rhythm problems (e.g. 2nd and 3rd degree atrioventricular block, heart conduction disorders) with symptoms such as shortness of breath, chest pain, dizziness, fainting and tiredness.
- You have heart failure, which has just occurred or which has recently become worse, or you are receiving treatment by intravenous drip for circulatory shock due to acute heart failure to help your heart work.
- You have untreated phaeochromocytoma (a tumour located on top of the kidneys) characterised by symptoms such as high blood pressure, fast heartbeat, heavy sweating, headache.
- You have serious circulation problems in the arms or legs.
- You have asthma or wheezing (now or in the past).
- You are taking verapamil (used to treat chest pain and irregular heart rhythms).
- You have metabolic acidosis (a condition in which too much acid accumulates in your body with symptoms such as nausea, vomiting, fast breathing, lack of energy).

Warnings and precautions

Take special care with NEBILET 5 mg:

Tell your health care provider if you have or develop one of the following problems:

- NEBILET 5 mg can worsen your sensitivity to allergy causing substances and the severity of those allergic reactions.
- A type of chest pain due to spontaneously occurring heart cramp called Prinzmetal angina.
- 1st degree heart block (a kind of light heart conduction disorder that affects your heart rhythm).
- Poor circulation in the arms or legs, e.g. Raynaud's disease or syndrome, cramp-like pains when walking.
- Diabetes: NEBILET 5 mg has no effect on blood sugar, but it could conceal the warning signs (abnormal or irregular heartbeats) of low blood sugar levels.
- Overactive thyroid gland: NEBILET 5 mg may mask the signs of an abnormally fast heart rate due to this condition. Abrupt withdrawal may intensify symptoms.
- Prolonged breathing problems as NEBILET 5 mg may aggravate airway constriction.
- If you need to have surgery, tell your anaesthetist that you are taking NEBILET 5 mg before being anaesthetised. Stop taking NEBILET 5 mg at least 24 hours before surgery.
- Psoriasis (a skin condition distinguished by scaly pink patches) or if you ever had psoriasis.

Tell your doctor if you have serious kidney problems as you are not supposed to be taking NEBILET 5 mg for heart failure.

Children and adolescents

Do not give NEBILET 5 mg to children below 18 years of age as the safety and efficacy have not been established.

Other medicines and NEBILET 5 mg

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Always tell your doctor if you are taking any of the following medicines in addition to NEBILET 5 mg as concomitant use may influence your blood pressure and heart function:

- Medicines for controlling the blood pressure or medicines for heart problems such as amiodarone, amlodipine, cibenzoline, clonidine, digoxin, diltiazem, disopyramide, felodipine, flecainide, guanfacine, hydroquinidine, lacidipine, lidocaine, methyldopa, mexiletine, moxonidine, nicardipine, nifedipine, nimodipine, nitrendipine, propafenone, quinidine, rilmenidine, verapamil.
- Sedatives and therapies for psychosis (a mental illness) such as barbiturates (also used for epilepsy), phenothiazine (also used for vomiting and nausea) and thioridazine.
- Medicines for depression such as amitriptyline, paroxetine, fluoxetine.
- Medicines used for anaesthesia during an operation.
- Medicines for asthma, blocked nose or certain eye disorders such as glaucoma (increased pressure in the eye) or dilation (widening) of the pupil.
- Baclofen (an antispasmodic medicine).
- Amifostine (a protective medicine used during cancer treatment).
- Concomitant treatment with an antacid: always take NEBILET 5 mg with a meal and take the antacid between meals.

NEBILET with food and drink

NEBILET 5 mg may be taken with or without food. The tablet is best taken with some water.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking NEBILET 5 mg.

Do not take NEBILET while you are pregnant or breastfeeding.

Driving and using machines

NEBILET 5 mg may cause side effects such as dizziness and fatigue which may affect your ability to drive a vehicle and use machines. Do not drive a vehicle or use machines if you experience these side effects.

It is not always possible to predict to what extent NEBILET 5 mg may interfere with your daily activities. You should not engage in the above activities until you are aware of the measure to which NEBILET 5 mg affects you.

NEBILET 5 mg contains lactose monohydrate and sodium

NEBILET 5 mg contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NEBILET 5 mg.

NEBILET 5 mg contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially sodium-free.

3. How to take NEBILET

Do not share medicines prescribed for you with any other person.

Always take NEBILET 5 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you have high blood pressure (adults only):

The usual dose is 5 mg (one tablet) per day, with or without meals, preferably at the same time every day.

NEBILET 5 mg can be used alone or in combination with other blood pressure-lowering medicines.

If you have kidney problems:

The starting dose is 2,5 mg (half a tablet) per day. Your doctor may increase your dose to 5 mg (one tablet) per day.

If you have liver problems:

Do not take NEBILET 5 mg.

Elderly adults (over 65 years):

The starting dose is 2,5 mg (half a tablet) per day. Your doctor may increase your dose to 5 mg (one tablet) per day, if needed.

If you are suffering from chronic heart failure (adults, including elderly adults):

The initial dose is 1,25 mg (a quarter of a tablet) once daily. Your doctor will prescribe a suitable dose for you.

The maximum dose is 10 mg (2 tablets).

Do not take NEBILET if you also have liver impairment and/or kidney impairment.

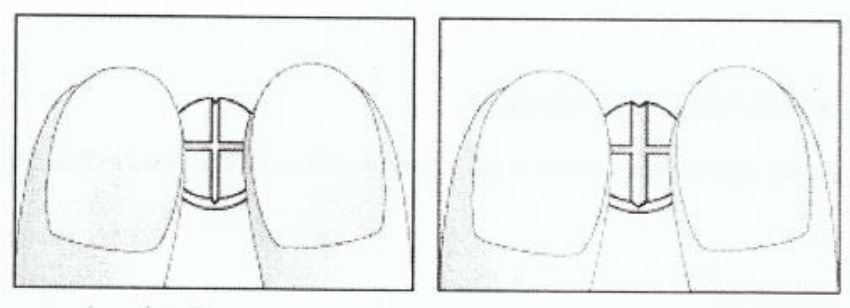
Your doctor will tell you how long your treatment with NEBILET 5 mg will last. Do not stop treatment early because you may aggravate your heart problems. Seek advice from your doctor on how to discontinue NEBILET 5 mg therapy.

If you have the impression that the effect of NEBILET 5 mg is too strong or too weak, tell your doctor or pharmacist.

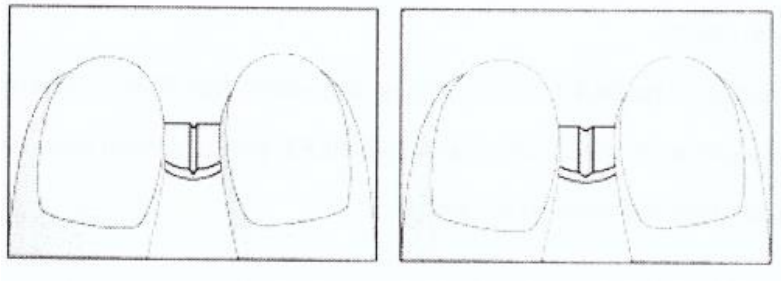
If you have been told by your doctor to take a ¼ (quarter) or ½ (half) tablet daily, please refer to the instructions below on how to break NEBILET 5 mg cross-scored tablets.

- Place the tablets onto a flat, hard surface (e.g. a table or worktop), with the cross score facing up.
- Break the tablet by pushing it with the index fingers of both hands placed along one break mark (Diagrams 1 and 2).
- Tablet quarters are obtained by breaking the halves in the same way (Diagrams 3 and 4).

Diagrams 1 and 2: Easy breaking of the NEBILET 5 mg cross-scored tablet in half.



Diagrams 3 and 4: Easy breaking of half of the NEBILET 5 mg cross-scored tablet into quarters.



If you take more NEBILET 5 mg than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

The most frequent symptoms and signs of a NEBILET 5 mg overdose are very slow heartbeat (bradycardia), low blood pressure with possible fainting (hypotension), breathlessness such as in asthma (bronchospasm), and acute heart failure.

If you forget to take NEBILET 5 mg

Do not take a double dose to make up for forgotten individual doses.

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take NEBILET 5 mg at the next regularly scheduled time.

If you stop taking NEBILET 5 mg

Do not stop taking NEBILET 5 mg suddenly without consulting your doctor. Your doctor will tell you how to stop taking NEBILET 5 mg without putting yourself at risk of more heart associated problems. Your heart condition may be aggravated if you stop taking NEBILET 5 mg suddenly.

4. Possible side effects

NEBILET 5 mg can have side effects.

Not all side effects reported for NEBILET 5 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NEBILET 5 mg, please consult your health care provider for advice.

If any of the following happens, stop taking NEBILET 5 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NEBILET 5 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Worsening of heart failure.
- Difficulty breathing.
- Feeling asthmatic or showing symptoms of bronchitis such as coughing and chest pain.
- Changes in the way your heart beats, for example, if you notice it beating faster or slower.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Dizziness.
- Headache.
- Fatigue.
- Tingling or numbness of your hands and feet (pins and needles).
- Constipation.
- Nausea.
- Diarrhoea.

Less frequent side effects:

- Nightmares.
- Depression.
- Impaired vision.
- Light-headedness.
- Indigestion.
- Flatulence or passing gas.
- Vomiting.
- Red patches of skin covered with silvery scales.
- Impotence (inability to get or maintain an erection).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the 6.04 Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of NEBILET 5 mg.

5. How to store NEBILET 5 mg

- Store at or below 25 °C.
- Do not use after the expiry date stated on the label.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What NEBILET 5 mg contains

The active substance is nebivolol hydrochloride.

Each tablet contains 5 mg nebivolol (as nebivolol hydrochloride).

The other ingredients are colloidal anhydrous silica (E551), croscarmellose sodium (E468), hypromellose (E464), lactose monohydrate, magnesium stearate (E572), maize starch, microcrystalline cellulose (E460) and polysorbate 80 (E433).

What NEBILET 5 mg looks like and contents of the pack

An off-white, circular, biconvex tablet with one-sided dividing cross score. The tablet can be divided in equal quarters.

Tablets are packed in PVC/aluminium blister strips, in an outer cardboard carton in pack sizes of 28 or 30.

Not all pack sizes may be marketed.

Holder of certificate of registration

Menarini South Africa (Pty) Ltd

Waterside Place, Unit 02D, South Gate Office Park

Carl Cronje Drive, Tygervalley

Cape Town 7530

Tel.: +27 21 109 6444

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