

NEBILET 5mg TABLETS

Nebivolol

What is in this leaflet

1. What is Nebilet 5mg tablets used for.
2. How Nebilet 5mg tablets works.
3. Before you take Nebilet 5mg tablets
4. How to take Nebilet 5mg tablets.
5. Side effects
6. After using Nebilet 5mg tablets
7. Product description
8. Manufacturer
9. Product Registration Holder
10. Date of revision.

What is Nebilet 5mg tablets used for.

Nebilet 5mg tablets is used to treat raised blood pressure (hypertension).

Nebilet 5mg tablets is also used to treat mild and moderate chronic heart failure in patients aged 70 or over, in addition to other therapies.

How Nebilet 5mg tablets works

Nebilet 5mg tablets contains nebivolol, a cardiovascular drug belonging to the group of selective beta-blocking agents (i.e. with a selective action on the cardiovascular system). It prevents increased heart rate, controls heart pumping strength. It also exerts a dilating action on blood vessels, which contributes as well to lower blood pressure

Before you take Nebilet 5mg tablets

- When you must not take it

Do not take Nebilet 5mg tablets

- if you are allergic (hypersensitive) to nebivolol

or any of the other ingredients of Nebilet 5mg tablets

- if you have one or more of the following disorders:
- low blood pressure
- serious circulation problems in the arms or legs
- very slow heartbeat (less than 60 beats per minute)
- certain other serious heart rhythm problems (e.g. 2nd and 3rd degree atrioventricular block, heart conduction disorders).
- heart failure, which has just occurred or which has recently become worse, or you are receiving treatment for circulatory shock due to acute heart failure by intravenous drip feed to help your heart work
- asthma or wheezing (now or in the past)
- untreated phaeochromocytoma, a tumour located on top of the kidneys (in the adrenal glands)
- liver function disorder
- a metabolic disorder (metabolic acidosis), for example, diabetic ketoacidosis.

- Before you start to take it

Take special care with Nebilet 5mg tablets

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
- allergy: This medicine may intensify your reaction to pollen or other substances you are allergic to
- psoriasis (a skin disease - scaly pink patches)
- if you have to have surgery, always inform your anaesthetist that you are on Nebilet 5mg tablets before being anaesthetised.

If you have serious kidney problems do not take Nebilet 5mg tablets for heart failure and tell your doctor.

You will be regularly monitored at the beginning of your treatment for chronic heart failure by an experienced physician (see 'How to Take').

This treatment should not be stopped abruptly unless clearly indicated and evaluated by your doctor (see 'How to Take').

- Children and adolescents

Because of the lack of data on the use of the product in children and adolescents, Nebilet 5mg tablets is not recommended for use in them.

- 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. Certain medicines cannot be used at the same time, while other drugs require specific changes (in the dose, for example).

Always tell your doctor if you are using or receiving any of the following medicines in addition to Nebilet 5mg tablets:

- Medicines for controlling blood pressure or medicines for heart problems (such as amiodarone, amlodipine, cibenzoline, clonidine, digoxin, diltiazem, disopyramide, felodipine, flecainide, guanfacin, hydroquinidine, lacidipine, lidocaine, methyl dopa, mexiletine, moxonidine, nicardipine, nifedipine, nimodipine, nitrendipine, propafenone, quinidine, rilmenidine, verapamil).
- Sedatives and therapies for psychosis (a mental illness) e.g. barbiturates (also used for epilepsy), phenothiazine (also used for vomiting and nausea) and thioridazine.
- Medicines for depression e.g. 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 drug); Amifostine (a protective medicine used during cancer treatment)

All these drugs as well as nebivolol may influence the blood pressure and/or heart function.

- Medicines for treating excessive stomach acid or ulcers (antacid drug), e.g. cimetidine: you should take Nebilet 5mg tablets during a meal and the antacid drug between meals.

- Taking Nebilet 5mg tablets with food and drink

Nebilet 5mg tablets can be taken with food or on an empty stomach, but the tablet is best taken with some water.

- Pregnancy and breast-feeding

Nebilet 5mg tablets should not be used during pregnancy, unless clearly necessary.

It is not recommended for use while breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

- Driving or operating machinery

This medicine may cause dizziness or fatigue. If affected, do not drive or operate machinery.

- Important information about some of the ingredients of Nebilet 5mg tablets

This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

How to take Nebilet 5mg tablets.

Always take Nebilet 5mg tablets exactly as your doctor has told you. You should check with your doctor if you are not sure.

Nebilet 5mg tablets may be taken before, during or after the meal, but, alternatively, you can take it independently of meals. The tablet is best taken with some water.

- Treatment of raised blood pressure (hypertension)

The usual dose is 1 tablet per day. The dose should be taken

preferably at the same time of the day.

Elderly patients and patients with a kidney disorder will usually start with ½ (half) tablet daily.

The therapeutic effect on blood pressure becomes evident after 1-2 weeks of treatment. Occasionally, the optimal effect is reached only after 4 weeks.

- Treatment of chronic heart failure

Your treatment will be started and closely supervised by an experienced physician.

Your doctor will start your treatment with ¼ (quarter) tablet per day. This may be increased after 1-2 weeks to ½ (half) tablet per day, then to 1 tablet per day and then to 2 tablets per day until the correct dose is reached for you. Your doctor will prescribe the dose that is right for you at each step and you should closely follow his/her instructions.

The maximum recommended dose is 2 tablets (10mg) a day.

You will need to be under the close supervision for 2 hours by an experienced physician when you start treatment and every time your dose is increased

Your doctor may reduce your dose if necessary

You should not stop treatment abruptly as this can make your heart failure worse.

Patients with serious kidney problems should not take this medicine.

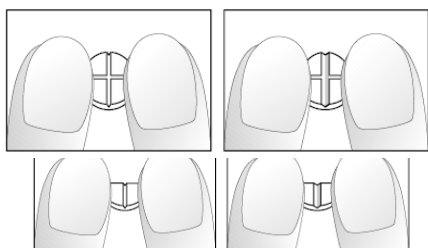
Take your medicine once daily, preferably at about the same time of day.

If you have been told by your doctor to take 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 breakmark (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 Nebivolol 5 mg cross-scored tablet in half.

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

Your doctor may decide to combine Nebilet 5mg tablets with other medicines to treat your condition.

Do not use in children or adolescents.

- If you take too much (overdose)

If you accidentally take an overdose of this medicine, tell your doctor or pharmacist immediately. The most frequent symptoms and signs of a Nebilet 5mg tablets overdose are very slow heart beat (bradycardia), low blood pressure with possible fainting (hypotension), breathlessness such as in asthma (bronchospasm), and acute heart failure.

You can take activated charcoal (which is available at your pharmacy) while you wait for the arrival of the doctor.

- If you forget to take it

If you forget a dose of Nebilet 5mg tablets, but remember a little

later on that you should have taken it, take that day's dose as usual. However, if a long delay has occurred (e.g. several hours), so that the next due dose is near, skip the forgotten dose and take the next, scheduled, normal dose at the usual time. Do not take a double dose. Repeated skipping, however, should be avoided.

- If you stop taking it

You should always consult with your doctor before stopping Nebilet 5mg tablets treatment, whether you are taking it for high blood pressure or chronic heart failure.

You should not stop Nebilet 5mg tablets treatment abruptly as this can temporarily make your heart failure worse. If it is necessary to stop Nebilet 5mg tablets treatment for chronic heart failure, the daily dose should be decreased gradually, by halving the dose, at weekly intervals.

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

Side effects

Like all medicines, Nebilet 5mg tablets can cause side effects, although not everybody gets them.

When Nebilet 5mg tablets is used for the treatment of raised blood pressure, the possible side effects are:

Common side effects (more than 1 person in every 100 treated but fewer than 1 person in every 10 treated):

- headache
- dizziness
- tiredness
- an unusual itching or tingling feeling
- diarrhoea
- constipation
- nausea
- shortness of breath

- swollen hands or feet.

Uncommon side effects (more than 1 person in every 1,000 treated, but fewer than 1 person in every 100 treated):

- slow heartbeat or other heart complaints
- low blood pressure
- cramp-like leg pains on walking
- abnormal vision
- impotence
- feelings of depression
- digestive difficulties (dyspepsia), gas in stomach or bowel, vomiting
- skin rash, itchiness
- breathlessness such as in asthma, due to sudden cramps in the muscles around the airways (bronchospasm)
- nightmares.

Very rare side effects (fewer than 1 person in every 10,000 treated):

- fainting
- worsening of psoriasis (a skin disease - scaly pink patches).

The following side effects have been reported only in some isolated cases during Nebilet 5mg tabletstreatment :

- whole-body allergic reactions, with generalised skin eruption (hypersensitivity reactions);
- rapid-onset swelling, especially around the lips, eyes, or of the tongue with possible sudden difficulty breathing (angioedema).

In a clinical study for chronic heart failure, the following side effects were seen:

Very common side effects (more than 1 person in every 10 treated):

- slow heart beat
- dizziness

Common side effects (more than 1 person in every 100 but less than 1 person in every 10 treated):

- worsening of heart failure
- low blood pressure (such as feeling faint when getting up quickly)
- inability to tolerate this medicine
- a kind of light heart conduction disorder that affects heart rhythm (1st degree AV-block)
- swelling of the lower limbs (such as swollen ankles).

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 npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

After using Nebilet 5mg tablets

- Storage

Remember to keep NEBILET 5mg tablets and all medications safely away from children.

Do not use this medicine after the month and year written after EXP on the container.

Store NEBILET 5mg tablets at room temperature (below 25°C).

- Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product Description

- What it looks like?

Nebilet 5mg tablets is available as white, round, cross-scored tablets

in packs of 7, 14, 28, 30, 50, 56, 90, 100, 500 tablets. Tablets are provided in blister packs (PVC/aluminium blister).

(Not all pack sizes may be marketed)

- Ingredients

The active substance is nebivolol. Each tablet contains 5 mg nebivolol (as nebivolol hydrochloride): 2.5 mg of d-nebivolol and 2.5 mg of l-nebivolol.

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

- Malaysian Registration Number

MAL 20041163AZ

Manufacturer

Berlin-Chemie AG

Glienicker Weg 125, 12489 Berlin, Germany

Product Registration Holder

A.Menarini (Singapore) Pte. Ltd.
B-18-2, Level 18, The Ascent Paradigm,
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