

Package leaflet: Information for the user

Nebivolol 5 mg tablets

Nebivolol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Nebivolol tablet is and what it is used for

Nebivolol tablet 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.

Nebivolol is used to treat raised blood pressure (hypertension).

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

2. What you need to know before you take Nebivolol

Do not take Nebivolol tablet:

- if you are allergic to the active substance of this medicine (nebivolol) or any of the other ingredients of this medicine (listed in section 6).
- 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nebivolol tablet

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) or if you have ever had psoriasis
- if you have to have surgery, always inform your anaesthetist that you are on Nebivolol before being anaesthetised

If you have serious kidney problems do not take Nebivolol tablet 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 section 3).

This treatment should not be stopped abruptly unless clearly indicated and evaluated by your doctor (see section 3).

Children and adolescents

Nebivolol is **not** recommended for use in children and adolescents because of the lack of data on the use of this medicine.

Other medicines and Nebivolol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Always tell your doctor if you are using or receiving any of the following medicines in addition to Nebivolol tablet:

- Medicines for controlling the 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 used in the treatment of psychosis (a mental illness) e.g. barbiturates (also used for epilepsy), phenothiazine (also used for vomiting and nausea) and thioridazine.
- Medicines used to treat depression e.g. amitriptyline, paroxetine, fluoxetine.
- Medicines used for anaesthesia during an operation.
- Medicines used 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)
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All these drugs as well as nebivolol (the active substance of this medicine) may influence the blood pressure and/or heart function.

- Medicines for treating excessive stomach acid or ulcers (antacid drug): you should take Nebivolol tablet during a meal and the antacid drug between meals.

Nebivolol tablet with food and drink

Please refer to section 3.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Nebivolol should not be used during pregnancy unless clearly necessary.

Breast-feeding

Breast-feeding is not recommended during treatment with Nebivolol.

Driving and using machines

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

Nebivolol tablet 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.

Nebivolol contains sodium

This medicine contains less than 1 mmol sodium (23mg) per film-coated tablet, that is so to say essentially 'sodium-free'.

3. How to take Nebivolol tablet

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Nebivolol tablet may be taken before, during or after the meal. Alternatively, you can take it independently of meals. The tablet is best taken with some water.

The tablet can be divided in four equal parts (4 doses of 1.25 mg).

Treatment of raised blood pressure (hypertension)

- The usual dose is 5 mg (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 2.5 mg (half a 5 mg 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 1.25 mg (quarter of a 5 mg tablet) per day. This may be increased after 1-2 weeks to 2.5 mg (half a 5 mg tablet) per day, then to 5 mg (1 tablet) per day and then to 10 mg (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.

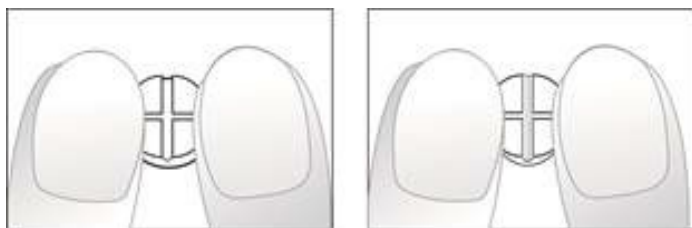
- You will need to be under the close supervision for 2 hours by an experienced physician when you start treatment and every time your dose is increased
- Your doctor may reduce your dose if necessary
- You should **not stop treatment abruptly** as this can make your heart failure worse.
- Patients with serious kidney problems should not take this medicine.
- Take your medicine once daily, preferably at about the same time of day.
- Your doctor may decide to combine Nebivolol tablet with other medicines to treat your condition.

Use in children and adolescents

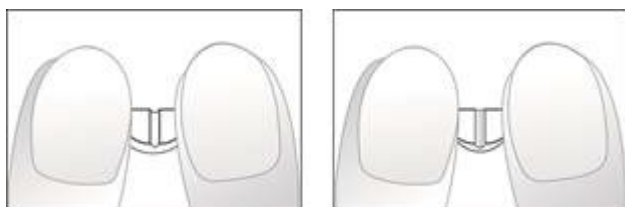
Nebivolol is not recommended in children or adolescents.

If you have been told by your doctor to take $\frac{1}{4}$ (quarter) or $\frac{1}{2}$ (half) tablet daily, please refer to the instructions below on how to break Nebivolol 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.

If you take more Nebivolol tablets than you should

If you accidentally take an overdose of this medicine, tell your doctor or pharmacist **immediately**. The most frequent symptoms and signs of a Nebivolol 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 Nebivolol tablet

If you forget a dose of Nebivolol tablet, 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 Nebivolol tablet

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

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

If it is necessary to stop Nebivolol tablet 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

When Nebivolol tablet is **used for the treatment of raised blood pressure**, the possible side effects are:

Common (may affect up to 1 in 10 people):

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

Uncommon (may affect up to 1 in 100 people):

- 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 (may affect up to 1 in 10,000 people)

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

The following side effects have been reported only in some isolated cases:

- 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);
- kind of skin rash notable for pale red, raised, itchy bumps of allergic or non allergic causes (urticaria).

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

Very common (may affect more than 1 in 10 people):

- slow heart beat
- dizziness

Common (may affect up to 1 in 10 people):

- worsening of heart failure
- low blood pressure (such as feeling faint when getting up too 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).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nebivolol

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton label and blister foil after EXP. The expiry date refers to the last day of that month.

Do not throw any medicine via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Nebivolol tablet contains

- The active substance is nebivolol. Each tablet contains 5 mg nebivolol (as nebivolol hydrochloride).
- The other ingredients are: lactose monohydrate, maize starch, croscarmellose sodium (E468), hypromellose (E464), polysorbate 80 (E433), cellulose, microcrystalline (E460), silica, colloidal anhydrous (E551), magnesium stearate (E572).

What Nebivolol tablets looks like and contents of the pack

Nebivolol tablet is available as white to off-white, round, biconvex tablets, approx. 9 mm in diameter, debossed with cross score line on one side and 'H' on the other side in packs of 28 tablets. Tablets are provided in blister pack (PVC/PVdC-aluminium blister).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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