



**Package leaflet:  
Information for the user**  
**Nebivolol 2.5 mg  
tablets**  
**Nebivolol 5 mg  
tablets**  
**nebivolol**

**Read all of this leaflet carefully before you start taking 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. 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 is and what it is used for**

Nebivolol 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 the blood pressure.

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

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

**2. What you need to know before you take Nebivolol**

**Do not take Nebivolol**

- If you are allergic to 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 heart beats per minute)
  - certain other serious heart rhythm problems (e.g. 2<sup>nd</sup> and 3<sup>rd</sup> 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.

Inform your doctor if you have or develop any 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.
- 1<sup>st</sup> degree heart block (a kind of light heart conduction disorder that affects the 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 a serious kidney problems do not take Nebivolol 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:

- Medicines for controlling the blood pressure or medicines used for heart problems (such as amiodarone, amlodipine, cibenzoline, clonidine, digoxin, diltiazem, disopyramide, felodipine, flecainide, guanfacin, hydroquinidine, lacidipine, lidocaine, methyl dopa, mexiletine, moxonidine, nifedipine, nicardipine, 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).

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

- Medicines used for treating excessive stomach acid or ulcers (antacid drug), you should take this medicine during a meal and take the antacid medicine between meals.

**Nebivolol 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 contains lactose**

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

**Nebivolol contains sodium**

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

**3. How to take Nebivolol**

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

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

**Treatment of raised blood pressure (hypertension)**

- The recommended dose is 5mg (one 5mg tablet or two 2.5 mg tablets) 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 or one 2.5 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.

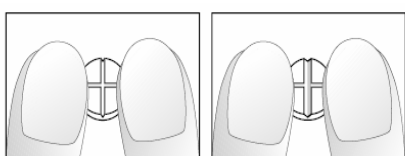
**Treatment of chronic heart failure**

- Your treatment will be started and closely supervised by an experienced physician.
- Your doctor will start your treatment with 1.25 mg (half a 2.5 mg tablet) per day. This may be increased after 1-2 weeks to 2.5 mg (one 2.5 mg tablet or half a 5 mg tablet) per day, then to 5 mg (two 2.5 mg tablets or one 5 mg tablet) per day and then to 10 mg (four 2.5 mg tablets or two 5 mg 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 your doctor's instructions.
- The maximum recommended dose is 10 mg per 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 each day.

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- Your doctor may decide to combine your tablets with other medicines to treat for your condition.
- For 5 mg**  
If you have been told by your doctor to take ¼ (i.e 1.25 mg-quarter) or ½ (i.e 2.5 mg-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.

#### Use in children and adolescents

Nebivolol is not recommended in children and adolescents.

#### If you take more Nebivolol 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 are waiting for your doctor to arrive.

#### If you forget to take Nebivolol

If you forget to take your medicine, but remember a little later that you should have taken it, take that day's dose as usual. However, if a long delay has occurred (e.g. after 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 to make up for a forgotten dose. Repeated skipping, however, should be avoided.

#### If you stop taking Nebivolol

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

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

If it is necessary to stop Nebivolol treatment for chronic heart failure, the daily dose should be decreased gradually, by halving the dose in weekly intervals.

If you have any further questions on the use of this medicine, 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 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 during treatment

with this medicine:

- whole-body allergic reactions, with generalised skin eruption (hypersensitivity reactions)
- rapid-onset of swelling, especially around the lips, eyes, or of the tongue with possible sudden difficulties in 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 quickly)
- inability to tolerate this medicine
- a kind of light heart conduction disorder that affects the heart rhythm (1<sup>st</sup> 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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://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.

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

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

#### What Nebivolol contains

- The active substance is nebivolol  
Each tablet contains 2.725 mg nebivolol hydrochloride equivalent to 2.5 mg nebivolol.  
Each tablet contains 5.45 mg nebivolol hydrochloride equivalent to 5 mg nebivolol.
- The other ingredients are lactose monohydrate, maize starch, croscarmellose sodium, hypromellose 15 cp, polysorbate 80, silica colloidal anhydrous, cellulose, microcrystalline (grade-102), magnesium stearate

#### What Nebivolol looks like and contents of the pack

Tablet.

##### Nebivolol 2.5 mg tablets:

White to off white, round shaped (diameter is 9.1 mm), biconvex uncoated tablets debossed with 'NL' on one side and '2 5' separated by score line on another side. The tablet can be divided into equal doses (halves).

##### Nebivolol 5 mg tablets:

White to off white, round shaped (diameter is 9.1 mm), biconvex uncoated tablets debossed with N L 5 separated by cross score line on one side of the tablet and plain on another side. The tablet can be divided into equal doses (halves and quarters).

Nebivolol tablets are available in blister pack and HDPE bottle pack with polypropylene closure.

Pack sizes:

Blister packs: 14, 28, 30, 50, 60, 90 and 100 tablets

HDPE packs (only for 5 mg): 250 tablets

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

Milpharm Limited  
Ares Block, Odyssey Business Park  
West End Road  
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#### Manufacturer

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