Package leaflet: Information for the user

Nebivolol 2.5 mg Tablets

Nebivolol 5 mg Tablets

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

1. What Nebivolol Tablets 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 blood pressure.

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

Nebivolol Tablets 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 Tablets

Do not take Nebivolol Tablets:

- 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. 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 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) and could increase the risk of severe hypoglycaemia when used with certain type of antidiabetic drugs called sulfonylureas (e.g. gliquidone, gliclazide, glibenclamide, glipizide, glimepiride or tolbutamide)
• 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
• if you have or previously had psoriasis (a skin disease - scaly pink patches)
• if you intend to have surgery, tell your doctor that you are taking Nebivolol Tablets before undergoing any surgery.

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

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

Children and adolescents

Because of the lack of data on the use of the product in children and adolescents, Nebivolol Tablets is **not** recommended for use in them.

Other medicines and Nebivolol Tablets

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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

- 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, methyldopa, mexiletine, moxonidine, nifedipine, nicardipine, 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).
- Medicines for diabetes such as insulin or oral antidiabetics drugs

All of these medicines as well as nebivolol may influence the blood pressure and/or your heart function if you are using or receiving any of the following medicines:

- Anti malarials (mefloquine).
- Medicines for treating excessive stomach acid or ulcers (antacid drug), you should take Nebivolol Tablets during a meal and the antacid medicine between meals.

Nebivolol Tablets with food and drink

Please refer to section 3.

Pregnancy and breast-feeding

Pregnancy

Nebivolol Tablets should not be taken during pregnancy unless clearly necessary.

Breast-feeding

It is not recommended for use while 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.

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

Nebivolol Tablets contains lactose
This medicine 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 Tablets 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 Tablets

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

Nebivolol Tablets 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 usual dose is 5mg (one 5mg tablet or two 2.5mg 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 2.5mg (half a 5mg tablet or one 2.5mg 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.

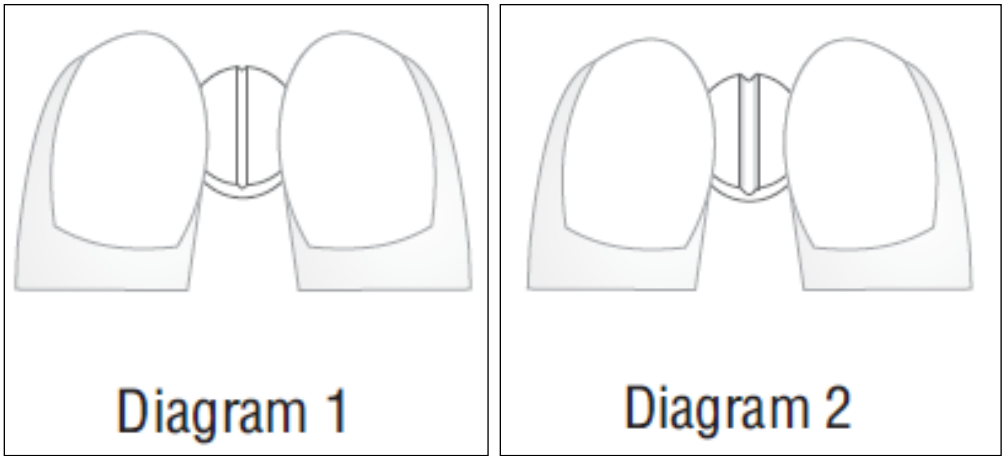
- Your doctor will start your treatment with 1.25mg (half a 2.5mg tablet) per day. This may be increased after 1-2 weeks to 2.5mg (one 2.5mg tablet or half a 5mg tablet) per day, then to 5mg (two 2.5mg tablets or one 5mg tablet) per day and then to 10mg (four 2.5mg tablets or two 5mg tablets) per day 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.

• 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 your tablets with other medicine for your condition.

- If you have been told by your doctor to take ½ (half) tablet daily, please refer to the instructions below on how to break Nebivolol 2.5mg and Nebivolol 5mg scored tablets into equal doses.

• Place the tablets onto a flat, hard surface (e.g. a table or worktop), with the break line facing up.
• Break the tablet by pushing it with the index fingers of both hands placed along break line (Diagrams 1 and 2).



Diagrams 1 and 2: Easy breaking of the Nebivolol 2.5mg and Nebivolol 5mg scored tablets into equal doses.

Use in children and adolescents
Do not use in children or adolescents.

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 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 Nebivolol Tablets
If you forget a dose of Nebivolol 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 scheduled usual time. Do not take a double dose. Repeated skipping, however, should be avoided.

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

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

If it is necessary to stop Nebivolol 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Nebivolol and talk to your doctor immediately if you have any of the following side effects:
- whole-body allergic reactions, with generalised skin eruption (hypersensitivity reactions)
- rapid-onset of swelling, especially around the lips, eyes, or of the tongue with sudden difficulties in breathing (angioedema).
- kind of skin rash notable for pale red, raised, itchy bumps of allergic or non allergic causes (urticaria).
- Breathlessness such as in asthma, due to sudden cramps in the muscles around the airways. Tightening of the chest, difficulty in breathing or wheezing (bronchospasm)

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

Common side effects (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 side effects (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 (difficulty in getting an erection)
- Feeling of depression
- Digestive difficulties (dyspepsia), gas in stomach or bowel (indigestion)
- Vomiting
- Skin rash, itchiness
- Breathlessness such as in asthma, due to sudden cramps in the muscles around the airways. Tightening of the chest, difficulty in breathing or wheezing (bronchospasm)
- Nightmares

Very rare side effects (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 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 side effects (may affect more than 1 in 10 people):

- slow heart beat

- dizziness

Common side effects (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 the 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nebivolol Tablets

Keep out of the sight and reach of children.

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

This medicinal product 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 to protect the environment.

If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Nebivolol Tablets contains

The active substance is nebivolol.
Each tablet contains 2.5mg of nebivolol equivalent to 2.725mg of nebivolol hydrochloride.
Or
Each tablet contains 5mg nebivolol equivalent to 5.45mg nebivolol hydrochloride

The other ingredients are:
lactose monohydrate; maize starch; croscarmellose sodium; hypromellose; microcrystalline cellulose; silica colloidal anhydrous; magnesium stearate.

What Nebivolol Tablets looks like and contents of the pack

Nebivolol 2.5mg Tablets: capsule shaped, white, biconvex uncoated tablets with a breakline on one side and plain on the other side. The tablet can be divided into equal doses.
Nebivolol 5mg Tablets: circular, white, biconvex uncoated tablets engraved with 'N' and 'L' on either side of the breakline on one side and plain on other side The tablet can be divided into equal doses.

Nebivolol 2.5mg and 5mg Tablets are available in PVC/PVdC/aluminium blisters and aluminium/ aluminium blisters of 14, 28, 30, 50, 90, 98, 100 tablets

*Not all pack sizes may be marketed.

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