Package leaflet: Information for the user

Nebivolol 10 mg Tablets

Nebivolol (as hydrochloride)

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 is and what it is used for

Nebivolol 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 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:
- 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
  - 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 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, as 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 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 is **not** recommended for use in them.

Other medicines and Nebivolol
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:

- 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, 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)
- medicines for diabetes such as insulin or oral antidiabetics drugs

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): you should Nebivolol during a meal and the antacid drug between meals.
- Anti malarials (mefloquine).

Nebivolol with food and drink

Please refer to section 3.

Pregnancy and breast-feeding

Beta-blockers, including nebivolol, can affect pregnancy and may harm the unborn baby. They can reduce blood flow to the placenta, which may lead to slower growth, miscarriage, premature birth or death of the foetus during pregnancy. Nebivolol should not be taken during pregnancy unless clearly necessary.

If nebivolol is required during pregnancy, close monitoring is required. After birth, your baby needs to be monitored for signs of low blood sugar (hypoglycaemia) and slow heart rate (bradycardia), which can occur within the first three days of life.

Mothers receiving Nebivolol should not breastfeed.

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 contains lactose

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.

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 Nebivolol exactly as your doctor 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 it independently of meals. The tablet is best taken with some water.

Treatment of raised blood pressure (hypertension)

- The usual dose is 5 mg (half a 10 mg tablet, one 5 mg 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*.

* Nebivolol 2.5 mg and 5 mg tablets are also available on the market.

- 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, one 5 mg tablet or half a 10 mg tablet) per day and then to 10 mg (four 2.5 mg tablets, two 5 mg tablets or one 10 mg tablet) 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 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 medicines for your condition

* Nebivolol 2.5 mg and 5 mg tablets are also available on the market.

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

If you take more Nebivolol than you should
If you accidentally take an overdose of this medicine, tell your doctor of 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
If you forget a dose of Nebivolol, 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
You should always consult with your doctor before stopping Nebivolol treatment, 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, 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.

When **Nebivolol are 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

The following side effects have been reported only in some isolated cases during nebivolol treatment (contact a doctor immediately)

- Whole body allergic reaction, with generalised skin eruption (hypersensitivity reactions)

*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
- 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 (*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 Nebivolol treatment:
- 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 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 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via:

Ireland
HPRA Pharmacovigilance,
Website: www.hpra.ie;

United Kingdom
Yellow Card Scheme
Website: 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

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

Do not use Nebivolol 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 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 contains

The active substance is nebivolol.
Each tablet contains 10 mg nebivolol equivalent to 10.9 mg nebivolol hydrochloride

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

What Nebivolol looks like and contents of the pack

Nebivolol 10 mg tablets: circular, white, shallow, biconvex uncoated tablets engraved with ‘G’ and ‘N’ on either side of break line on one side and plain on other side. The tablets can be divided into equal halves.

Nebivolol 10 mg tablets are available in PVC/PVdC/aluminium blisters and aluminium/ aluminium blisters of 14, 28, 30, 50, 100 tablets.

*Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Glenmark Arzneimittel GmbH
Industriestr. 31
82194 Gröbenzell
Germany

Manufacturers
Glenmark Pharmaceuticals Europe Limited,
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Croxley Green, Hertfordshire, WD18 8YA,
United Kingdom

Glenmark Pharmaceuticals s.r.o.
Fibíchova 143, 566 17 Vysoké Mýto
Czech Republic

Tillomed Laboratories Limited,
3 Howard Road, Eaton Socon, St Neots, Cambridgeshire,
PE19 8ET
United Kingdom

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Ireland, United Kingdom (Northern Ireland): Nebivolol 10 mg Tablets

This leaflet was last revised in.