PACKAGE LEAFLET

Package leaflet: Information for the patient

NEBIVOLOL 5 MG TABLETS

(nebivolol)

Read all of this leaflet carefully before you start taking this medicine because it might contain 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 belongs to a group of medicines called beta-blockers that are used to lower blood pressure.
Nebivolol is used to treat:
- high blood pressure (hypertension)
- elderly patients suffering from mild to moderate heart failure in addition to standard therapy (e.g. with diuretics, digoxin, ACE inhibitors, angiotensin II antagonists).

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). An allergic reaction may include rash, itching, swelling or difficulty breathing
- have liver problems
- have had a heart attack, have heart failure which might be getting worse or have had intravenous medical treatment for heart failure
- have missed heart beats (conditions such as sick sinus syndrome, sinoatrial block or second or third degree heart block) but have not been fitted with a pacemaker
- have or have had asthma or other serious breathing problems
- have a tumour of the adrenal gland called a phaeochromocytoma that is not being treated
- have a condition called metabolic acidosis
- suffer from a slow heart beat (fewer than 60 beats per minute, known as bradycardia)
- you suffer from low blood pressure or have very poor circulation
- use medicines containing floctafenine or sultopride.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nebivolol if you:
- have ongoing heart problems that are not being treated as Nebivolol may make these worse.
- have Raynaud's disease, poor circulation in the arms or legs or have periods when walking is difficult, including bouts of limping or lameness, as Nebivolol may make these conditions worse.

- have been told by a doctor that you have a first degree heart block (missed heart beats) as Nebivolol may make this worse or slow down your heart rate. Your doctor may want to monitor your heart rate and if necessary change your dosage.
- suffer from Prinzmetal's angina as Nebivolol may make your angina attacks worse.
- are diabetic as Nebivolol may mask some of the signs that your blood sugar levels are low (hypoglycaemia) 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).
- have an over active thyroid gland (hypothyroidism) as Nebivolol may mask some of the signs of this condition such as a fast heart rate (tachycardia).
- have problems with your lungs as Nebivolol can cause further breathing difficulties. Your doctor will advise you if you are at risk.
- have a skin condition called psoriasis or if you suffer from hay fever or have other allergies because Nebivolol may make these conditions worse. Talk to your doctor if you are unsure about whether to take this medication.
- wear contact lenses, as Nebivolol may cause dry eyes.

Other medicines and Nebivolol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription or the following.

Do not take Nebivolol if you are taking any medicines containing floctafenine or sultopride (see section 'Do not take' above).

Taking any of these medicines and Nebivolol may lower your blood pressure too much or cause heart problems:

- medicines to lower your blood pressure such as verapamil, diltiazem, clonidine, guanfacin, moxonidine, methyldopa, rilmenidine, amlodipine, felodipine, lacidipine, nifedipine, nicardipine, nimodipine, nitrendipine)
- medicines for diabetes such as insulin or oral antidiabetics drugs
- medicines to treat abnormal heart rhythms such as amiodarone, quinidine, hydroquinidine, cibenzoline, flecainide, disopyramide, lidocaine, mexiletine, propafenone
- medicines to treat depression or other mental problems such as paroxetine, fluoxetine, thioridazine.
- barbiturates (used for epilepsy, anxiety or insomnia)
- baclofen (a muscle relaxant)
- amifostine (used in cancer therapy)
- Mefloquine (antimalaria drug)
- Organic nitrates (to treat chest pain)
- Quinidine (used to slow down the heart)
- Terbinafine (for fungal or yeast infections)
- Bupropion (to help in cessation of smoking)
- Chloroquine (for malaria or rheumatoid arthritis)
- Levomepromazine (for mental health problems)

Also:

- stimulants containing dopamine or decongestants containing ephedrine as they may increase your blood pressure too much or cause heart problems.
- insulin or any oral anti-diabetic medicines because Nebivolol may mask symptoms of hypoglycaemia (low sugar level of the blood) like a racing heart beat or palpitations

Surgery

Nebivolol may react with certain anaesthetics used in operations. So in the event that you need any form of surgery, you should tell your doctor, dentist or the medical staff at the hospital that you are taking Nebivolol.

Pregnancy and breast-feeding

Nebivolol should not be given to pregnant or breast-feeding mothers unless the benefits to the mother outweigh the risks to the baby.

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 fainting as a result of a reduction in blood pressure. If these occur, do not drive or operate machinery. These effects are more likely to occur at the start of the treatment or after dose increases (see also section 4).

Nebivolol contains lactose and sodium

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

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.

Always check that you have enough tablets and do not run out. Try to take your tablets at the same time each day. Swallow the tablet with a glass of water. You may take your tablets with or without food.

The tablet can be divided into 4 equal doses.

Treatment for high blood pressure
Use in adults: The usual dose is 5 mg of Nebivolol once a day. It usually takes 1 – 2 weeks for the medicine to work but occasionally it may take up to 4 weeks.

Elderly: If you are over 65 years and taking Nebivolol to lower your blood pressure the usual starting dose is 2.5 mg per day. However, your doctor may increase this to 5 mg per day if they feel this is necessary.

Patients with kidney disease: The usual dose is 2.5 mg once a day. However, your doctor may increase your dose to 5 mg per day if required.

Patients taking Nebivolol and another medicine to lower your blood pressure
When taken with hydrochlorothiazide the usual daily dose is 5 mg of Nebivolol and 12.5 – 25 mg of hydrochlorothiazide per day.

Treatment for heart failure
Use in adults and the elderly: Your doctor will start you on a low dose and gradually increase your dose over 1 – 2 weekly intervals until your condition has stabilised. The usual starting dose is 1.25 mg once daily for 1 –2 weeks, this may be increased to 2.5 mg once daily, then to 5 mg once daily and then to 10 mg once daily. The maximum recommended dose is 10 mg once daily. Your doctor will tell you how much to take.

Patients with kidney disease
Nebivolol is not recommended for use in patients with severe kidney disease. Your doctor will advise you whether Nebivolol is suitable for your condition.

Patients with liver disease
If you suffer from liver disease **do not** take Nebivolol.

Use in children and adolescents
Nebivolol is not recommended for use in children or adolescents below 18 years.

If you take more Nebivolol than you should

Contact your doctor or casualty department immediately. Take the container and any remaining tablets with you. Signs and symptoms of overdose include: a slow heart rate, low blood pressure, wheezing and difficulty breathing and sudden heart problems.

If you forget to take Nebivolol

If you forget to take a dose of Nebivolol **do not** take a double dose to make up for a forgotten dose. Take the next dose on time. If you miss several doses contact your doctor.

If you stop taking Nebivolol

If you suddenly stop taking Nebivolol you are likely to suffer from side effects, or your illness may get worse. If you need to stop taking this medicine your doctor will reduce your dose slowly over a 2 week period.

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.

If any of the following happen, stop taking Nebivolol and tell your doctor immediately or go to your nearest hospital emergency department:
- tightness of the chest and difficulty breathing.
- serious allergic reactions which may cause a rash, itching, hives or swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- heart failure which may cause shortness of breath, getting tired easily after light physical activity or swelling of the feet or legs due to fluid build up
- changes in the electrical activity of your heart causing missed heart beats
- problems with your eye such as inflammation, dryness of the eye, redness or gritty-irritation of the eyelid which may cause damage to the eye
- mental health problems (psychoses) which may cause you to hear, see or feel things that aren't there (hallucinations), have false beliefs (delusions), be confused, have disturbed or unusual thoughts or behaviour

Other possible side effects include:

Common side effects (may affect up to 1 in 10 people):
- headaches
- tingling or pins and needles
- fainting on standing up
- constipation, feeling sick (nausea) or diarrhoea
- feeling tired
- fluid retention (swelling)
- shortness of breath

Uncommon side effects (may affect up to 1 in 100 people):
- nightmares

- feelings of depression
- problems with eyesightslow heartbeat or other heart complaints other changes in how your heart works, which can be seen during heart exams
- low blood pressure
- difficulty or pain walking including muscle cramps, limping or lameness
- breathlessness such as in asthma, due to sudden cramps in the muscles around the airways (bronchospasm)
- indigestion, flatulence (passing wind), being sick (vomiting)
- inability to get or maintain an erection
- skin rash, skin itchiness

Very rare side effects (may affect up to 1 in 10,000 people):
- fainting
- worsening of your psoriasis, or skin rash psoriasis-like (thickened patches of red skin, often with silvery scales)

Not known (the frequency cannot be estimated from the available data):
- 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).

The following side effects have been reported with medicines of the same type as nebivolol, so may be seen with this medicine. The frequency cannot be estimated from the available data:

- cold fingers and toes with bluish discolouration of the skin (Raynaud's phenomenon)
- dry eyes

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):
- dizziness
- slow heart rate

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)
- intolerance to Nebivolol
- 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. This includes any 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

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

This medicine does not require any special storage conditions.

Do not use this medicine if you notice any discolouration of the tablets.

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 5.45 mg of nebivolol hydrochloride equivalent to 5 mg of nebivolol**.**

The other ingredients are lactose monohydrate (see section 2 'Nebivolol contains lactose and sodium'), croscarmellose sodium, maize starch, polysorbate 80, hypromellose, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate.

What Nebivolol looks like and contents of the pack

Nebivolol Tablets are white, oval, 9.5 mm x 8.5 mm, quadrisected, flat-faced, bevelled-edged tablets. Each tablet is marked "N'' in the upper left quadrant and "L" in the upper right quadrant on one side only.

This medicine is available in PVC/PVdC – Alu blisters in packs of 7, 10, 14, 28, 30, 50, 56, 60, 84, 90, 98 and 100 tablets, in opaque plastic bottles containing 100 or 500 tablets or in PVC/PVdC – Alu perforated unit dose blisters in pack sizes of 28 x 1, 56 x 1, 100 x 1 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Mylan Hungary Kft, H-2900 Komárom, Mylan utca 1, Hungary

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