

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**NEBILET® 5MG TABLETS/  
 NEBIVOLOL 5MG TABLETS/  
 NEBILOX® 5MG TABLETS**  
 (neбиволол hydrochloride)

This product is available as any of the above names but will be referred to as Nebilet throughout the following patient information leaflet.

**Read all this leaflet carefully before you start using this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Nebilet is and what it is used for
2. Before you take Nebilet
3. How to take Nebilet
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**1. What Nebilet is and what it is used for**

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

**2. Before you take Nebilet**

**Do not take Nebilet**

- if you are allergic (hypersensitive) to neбиволол or any of the other ingredients of Nebilet
- 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.

**Take special care with Nebilet**

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
- 1<sup>st</sup> 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 Nebilet before being anaesthetised.

If you have serious kidney problems do not take Nebilet 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, Nebilet is **not** recommended for use in them.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, **including** medicines obtained without a prescription. Certain medicines cannot be used at the same time, while other drugs require specific changes (in the dose, for example).

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

- 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, rilmendine, 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.

**MOCK UP**

- 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)
- All these drugs as well as neбиволол may influence the blood pressure and/or heart function.
- Medicines for treating excessive stomach acid or ulcers (antacid drug), e.g. cimetidine: you should take Nebilet during a meal and the antacid drug between meals.

**Taking Nebilet with food and drink**

Nebilet can be taken with food or on an empty stomach, but the tablet is best taken with some water.

**Pregnancy and breast-feeding**

Nebilet should not be used during pregnancy, unless clearly necessary.

It is not recommended for use while breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving or operating machinery**

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

**Important information about some of the ingredients of Nebilet**

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.

**3. How to take Nebilet**

Always take Nebilet exactly as your doctor has told you. You should check with your doctor if you are not sure.

Nebilet 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)**

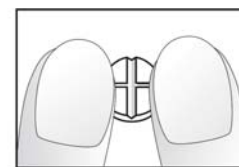
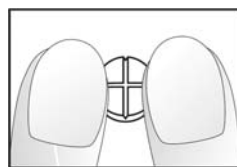
- The usual dose is 1 tablet per day. The dose should be taken preferably at the same time of the day.
- Elderly patients and patients with a kidney disorder will usually start with ½ (half) tablet daily.
- The therapeutic effect on blood pressure becomes evident after 1-2 weeks of treatment. Occasionally, the optimal effect is reached only after 4 weeks.

**Treatment of chronic heart failure**

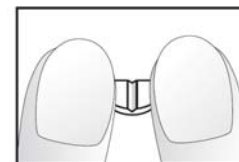
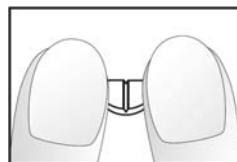
- Your treatment will be started and closely supervised by an experienced physician.
- Your doctor will start your treatment with ¼ (quarter) tablet per day. This may be increased after 1-2 weeks to ½ (half) tablet per day, then to 1 tablet per day and then to 2 tablets per day until the correct dose 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.

If you have been told by your doctor to take ¼ (quarter) or ½ (half) tablet daily, please refer to the instructions below on how to break Nebilet 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.

- Your doctor may decide to combine Nebilet tablets with other medicines to treat your condition.
- Do not use in children or adolescents.

#### If you take more Nebilet 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 Nebilet 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 Nebilet

If you forget a dose of Nebilet, 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 Nebilet

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

You should not stop Nebilet treatment abruptly as this can temporarily make your heart failure worse. If it is necessary to stop Nebilet 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, Nebilet can cause side effects, although not everybody gets them.

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

Common side effects (more than 1 person in every 100 treated but fewer than 1 person in every 10 treated):

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

Uncommon side effects (more than 1 person in every 1,000 treated, but fewer than 1 person in every 100 treated):

- 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 (fewer than 1 person in every 10,000 treated):

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

The following side effects have been reported only in some isolated cases during Nebilet 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).

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

Very common side effects (more than 1 person in every 10 treated):

- slow heart beat
- dizziness

Common side effects (more than 1 person in every 100 but less than 1 person in every 10 treated):

- 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 (1<sup>st</sup> degree AV-block)
- swelling of the lower limbs (such as swollen ankles).

**If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

#### 5. How to store Nebilet

- There are no special storage conditions for Nebilet.
- **KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.**
- Do not take Nebilet after the expiry date ('EXP') which is stated on the box and on the blister pack.
- Nebilet should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

#### 6. Further information

##### What Nebilet contains

- The active substance is Nebivolol 5mg (as nebivolol hydrochloride): each tablet contains 5.45 milligrams (mg) of nebivolol hydrochloride corresponding to 5mg of nebivolol.
- The other ingredients are: polysorbate 80, hypromellose, lactose, maize starch, croscarmellose sodium, microcrystalline cellulose, colloidal anhydrous silica and magnesium stearate.

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

Nebilet is available as white, round, biconvex tablets, scored on one face and plain on the other side in blister packs of 28 tablets.

##### Manufacturer and Licence holder

Nebilet is manufactured by Berlin Chemie AG, Glienicker Weg 125, D-12489 Berlin, Germany and are procured from within the EU by the Product Licence holder: G.Pharma Ltd., Salford, M50 2PU.

PL NO: 16369/1245

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This leaflet was last revised: 12/01/2012