

**Read all of this leaflet carefully before you start taking this medicine**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you only. 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, health care provider or pharmacist.

**In this leaflet:**

- a) What Nebilong is and what it is used for
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**a. What Nebilong is and what it is used for**

Nebilong contains Nebivolol, a cardiovascular drug belonging to the group of selective beta-blocking agents (i.e. with a selective action on the cardiovascular system).

**How Nebilong works**

It prevents increased heart rate and controls heart pumping strength. It also exerts a dilating action on blood vessels, which contributes 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.

**b. Before you take Nebilong**

**Do not take Nebilong:**

- If you are allergic to Nebilong 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 beats per minute)
- certain other serious heart rhythm problems (e.g. second and third 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)

If you have serious kidney problems do not take Nebilong 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.

This treatment should not be stopped abruptly unless clearly indicated and evaluated by your doctor.

### **Take special care with Nebilong**

Talk to your doctor or pharmacist before taking Nebilong.

It is important to tell your doctor if you have or develop one of the following conditions:

- abnormally slow heartbeat
- a type of chest pain due to spontaneously occurring heart cramp called Prinzmetal's angina
- untreated chronic heart failure
- first 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 mask the warning signs of a low sugar level (e.g. palpitations, fast heartbeat).
- 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 Nebilong before being anaesthetised.

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 (10 mg) 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.

Your doctor may decide to combine Nebivolol tablets with other medicines to treat your condition.

Use in children and adolescents

Nebilong is not recommended in children and adolescents.

Children and adolescents:

Because of the lack of data on the use of this medicine in children and adolescents, Nebilong is not recommended in children and adolescents below 18 years of age.

### **Taking Nebilong and Other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 Nebilong:

- Medicines for controlling blood pressure or medicines for heart problems (such as Amiodarone, amlodipine, cibenzoline, clonidine, digoxin, Diltiazem, disopyramide, felodipine, flecainide, guanfacine, 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)

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), e.g. cimetidine: you should take Nebivolol tablets during a meal, and the antacid drug between meals

### **Pregnancy, breast-feeding and fertility**

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.

Nebilong should not be used during pregnancy unless instructed to do so by a doctor.

Breast-feeding is not recommended during administration of Nebilong.

### **Driving and using machines**

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

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

### **c. How to take Nebilong**

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

Nebilong may be taken before, during or after the meal, but alternatively you can take it independently of meals.

The tablet or its parts 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 1/2 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.

### **If you take more Nebilong 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 wait for the arrival of the doctor.

### **If you forget to take Nebilong**

If you forget a dose of Nebilong, 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 to make up with a forgotten dose. Repeated skipping, however, should be avoided.

### **If you stop taking Nebilong**

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.

## **d. 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 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)

- 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).

**Not known (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).
- Hives

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

**Very common side effects (may affect more than 1 person 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 (1<sup>st</sup> degree AV-block),
- Swelling of the lower limbs (such as swollen ankles).

**e. How to store Nebilong**

Keep out of the reach and sight of children.

Do not store above 30°C.

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

Do not use Nebilong If you notice the visible signs of deterioration.

Medicines 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.

**f. Further information**

**What Nebilong contains**

The active substance is Nebivolol Hydrochloride.

The other ingredients are:

Lactose, Microcrystalline cellulose, Betadex (Betacyclodextrin), Croscarmellose sodium, Dioctyl Sodium Sulpho Succinate, Povidone, Isopropyl alcohol, Dichloromethane, Colloidal silicon dioxide, Magnesium stearate and Talc.

**What Nebilong looks like and contents of the pack**

Flat round, white or off white scored tablets with the breakline on one surface.

Alu-Alu pack of 10 Tablets.

**Name and full physical address of Marketing Authorization Holder and Manufacturing site**

**Marketing Authorization Holder**

M/S PHILLIPS PHARMACEUTICALS LTD

N5, Madhwani Godowns, 5th Street,

Industrial Area, Bugolobi,

Kampala

Uganda PO Box- 21428

**Manufacturer**

**MICRO LABS LIMITED**

92, SPICOT

HOSUR - 635126

INDIA

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