#### PATIENT INFORMATION LEAFLET

#### NEBIVOLOL HYDROCHLORIDE TABLETS 5 mg (NEBILONG 5)



#### 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 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 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>.>

#### **Prescription only medicine**

#### In this leaflet:

- a) What Nebilong is and what it is used for
- b) Before you take Nebilong
- c) How to take Nebilong
- d) Possible Side Effects
- e) How to store Nebilong
- f) Further information

#### a. What Nebilong is and what it is used for

Nebivolol is a kind of prescription medicine called a "beta-blocker". Nebivolol treats: High blood pressure (hypertension)

Nebivolol can lower blood pressure when used by itself and with other medicines.

Nebivolol is not approved for children less than 18 years of age.

### b. Before you take Nebilong

Do not take Nebivolol if you:

- Have heart failure and are in the ICU or need medicines to keep up your blood circulation
- Have a slow heartbeat or your heart skips beats (irregular heartbeat)
- Have severe liver damage

Are allergic to any ingredient in Nebivolol. The active ingredient is nebivolol. See the end of this leaflet for a list of ingredients.

#### WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING NEBIVOLOL?

Tell your doctor about all of your medical problems, including if you:

• Have asthma or other lung problems (such as bronchitis or emphysema)

- Have problems with blood flow in your feet and legs (peripheral vascular disease) Nebivolol can make symptoms of blood flow problems worse.
- Have diabetes and take medicine to control blood sugar
- Have thyroid problems
- Have liver or kidney problems
- Had allergic reactions to medications or have allergies
- Have a condition called pheochromocytoma
- Are pregnant or trying to become pregnant. It is not known if Nebivolol is safe for your unborn baby.
- Talk with your doctor about the best way to treat high blood pressure while you are pregnant.
- Are breastfeeding. It is not known if Nebivolol passes into your breast milk. You should not breastfeed while using Nebivolol.
- Are scheduled for surgery and will be given Anesthetic agents

Tell your doctor about all the medicines you take. Include prescription and non-prescription medicines, vitamins, and herbal products. Nebivolol and certain other medicines can affect each other and cause serious side effects. Keep a list of all the medicines you take. Show this list to your doctor and pharmacist before you start a new medicine.

#### **Nebivolol contains lactose**

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

#### c. How to take Nebilong

Do not suddenly stop taking Nebivolol. You could have chest pain or a heart attack. If your doctor decides to stop Nebivolol, your doctor may slowly lower your dose over time before stopping it completely.

Take Nebivolol every day exactly as your doctor tells you. Your doctor will tell you how much Nebivolol to take and how often. Your doctor may start with a low dose and raise it over time.

Do not stop taking Nebivolol or change your dose without talking with your doctor.

Take Nebivolol with or without food.

If you miss a dose, take your dose as soon as you remember, unless it is close to the time to take your next dose. Do not take 2 doses at the same time. Take your next dose at the usual time.

If you take too much Nebivolol, call your doctor or poison control center right away.

#### d. Possible side effects

Low blood pressure and feeling dizzy. If you feel dizzy, sit or lie down and tell your doctor right away.

**Tiredness** 

Slow heartbeat

#### Headache

Leg swelling due to fluid retention (edema). Tell your doctor if you gain weight or have trouble breathing while taking Nebivolol.

Tell your doctor if you have any side effects that bother you or don't go away.

#### e. How to store Nebilong

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

This medicinal product does not require any special storage conditions.

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

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.

#### f. further information

# What Nebilong contains

Active substance is: Nebivolol Hydrochloride

The other ingredients are: Lactose, Microcrystalline cellulose, Betadex, Croscarmellose Sodium, Dioctyl sodium sulpho succinate, Povidone, Colloidal anhydrous silica, Talc, Magnesium Stearate

## What Nebilong looks like and contents of the pack

White, flat, circular, beveledged uncoated tablets with a 'MICRO' engraved on one side and a breakline on another side.

Breakline is to facilitate breaking for ease of swallowing and not for dividing into equal doses.

Alu-Alu Blister pack of 3×10 Tablets

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

#### **Marketing Authorization Holder**

#### MICRO LABS LIMITED

31, Race course road

Bangalore-560001

**INDIA** 

#### Manufacturer

#### MICRO LABS LIMITED

No. 92, Sipcot Industrial Complex

Hosur -635 126 (TN)

**INDIA** 

For any information about this medicinal product, please contact the <local representative of the> supplier:

# **Country: Rwanda**

M/s.Wessex

Pharmaceuticals (Rwanda) Ltd

C/o.Phillips Pharmaceuticals (Rwanda) Ltd

Shop No: Gf68, Kigali Modern City Market Commercial Street

Kigali, Rwanda

This leaflet was last approved in

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