

Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your health care provider.
- 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider

WHAT IS IN THIS LEAFLET

- What NEBILONG- AM is and what it is used for
- What you need to know before you take NEBILONG- AM
- How to take NEBILONG- AM
- Possible Side Effects
- How to store NEBILONG- AM
- Contents of the pack and other information

WHAT NEBILONG- AM IS AND WHAT IT IS USED FOR

Nebilong – AM contains Nebivolol and Amlodipine as the active ingredients.

Nebivolol is 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 and controls heart pumping strength. It also widens blood vessels, which helps to lower your blood pressure and Amlodipine belong to a group of medicines called calcium antagonists. In patients with high blood pressure your medicine works by relaxing blood vessels, so that blood passes through them more easily.

Nebilong- AM is a one-tablet combination of nebivolol and Amlodipine and is used for the treatment of mild to moderate essential hypertension.

WHAT YOU NEED TO KNOW BEFORE YOU TAKE NEBILONG- AM

Contact your doctor if you are not sure if you belong to a patient group described below.

Do not take Nebilong - AM

- If you are allergic (hypersensitive) to nebivolol or to Amlodipine any of the other ingredients of Nebilong – AM.
- If you have low blood pressure (the systolic or “upper” pressure is less than 90 mmHg).
- If you have poor circulation in the arms or legs.
- If you have a very slow heartbeat (less than 60 heart beats per minute before having started this medication)
- If you have been diagnosed with conduction disorders in your heart (such as sick sinus syndrome or atrio-ventricular blockade) and you do not have a functioning pacemaker.
- If you have acute heart failure, or you are receiving treatment into a vein (by intravenous ‘drip’) to help your heart work.
- If you have difficulty in breathing or wheezing (or history of)
- If you have a tumour of the adrenal gland called phaeochromocytoma
- If you have severe liver disease or liver function impairment
- If you have a metabolic acidosis (such as in diabetic patients when the blood sugar has risen too much and blood has become too acidic)
- If you use either floctafenine or sultopride containing medications.

Talk to your doctor before taking Nebilong- AM

If you have or develop one of the following conditions:

- Heart failure (inability of heart to pump enough blood for body's needs)
- A mild (first degree) atrioventricular blockade in your heart
- Chest pain caused by cramping of the coronary arteries (called Prinzmetal's angina or variant angina)
- Poor circulation in the arms or legs, e.g. Reynaud's disease or syndrome, cramp-like pains on walking
- Prolonged breathing problems (or history of)
- Diabetes: Nebivolol has no effect on blood sugar, but it could mask the signs of a low sugar level (e.g. trembling, fast heartbeat).
- Overactive thyroid gland, as Nebivolol may mask the signs of an abnormally fast heart rate due to this condition
- Allergy, as the allergic reactions may become stronger and more medicines may be needed to treat them
- A skin condition known as psoriasis, as Nebivolol may aggravate the symptoms.
- Recent heart attack (within the last month)
- Severe increase in blood pressure (hypersensitive crisis).
- Liver disease.

In these cases, your doctor may need to adapt your treatment or check you more often.

Children and adolescents,

Use in children and adolescents below 18 years old is not recommended.

Other medicines and Nebilong- AM,

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, herbal remedies and strong vitamins and minerals.

Always tell your doctor or pharmacist if you are using or receiving any of the following medicines in addition to Nebilong- AM:

- Diltiazem or verapamil (used for high blood pressure and other heart problems). During Nebivolol treatment, verapamil should not be injected into a vein.
- other medicinal products known as calcium channel blockers for high blood pressure or other heart problems such as amlodipine, felodipine, lacidipine, nifedipine, nicardipine, nimodipine, nitrendipine
- Other antihypertensive medications or organic nitrates to treat chest pain.
- Clonidine, guanfacin, moxonidine, methyl dopa, rilmenidine used for the treatment of high blood pressure
- Medicinal products for cardiac arrhythmias (irregular heartbeat) such as quinidine, hydroquinidine, amiodarone, cibenzoline, flecainide, disopyramide, lidocaine, mexiletine, propafenone
- Tricyclic antidepressants (for depression), phenothiazines (for psychoses), or barbiturates (for epilepsy)
- Medicinal products for diabetes mellitus (insulin's and oral preparations)
- Digoxin or other so called digitalis glycosides (to treat heart failure)
- Anti-inflammatory analgesics (NSAIDs) for pain and inflammation- please note that small daily Antithrombotic doses of acetylsalicylic acid (e.g., 50 or 100 mg) can be used safely with Nebivolol
- Medicinal products for asthma, blocked nose or certain eye disorders such as glaucoma (increased pressure in the eye) or dilation of the pupil
- Anaesthetics: always inform your anaesthetist that you are on Nebivolol before being anaesthetized
- Cimetidine (to treat excessive stomach acid)- you should take Nebivolol during a meal, and the antacid drug between meals
- Medicinal products affecting the metabolism of nebivolol namely terbinafine (for fungal or yeast infections), bupropion (to help in cessation of smoking), chloroquine (for malaria or rheumatoid arthritis), levomepromazine (for psychoses), paroxetine, fluoxetine, thioridazine (for depression).
- Amifostine (a protecting substance during chemo- or radiation therapy).
- Baclofen (a muscle relaxant).
- Mefloquine (an antimalarial).

Pregnancy and breast-feeding

Pregnancy

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

Breast-feeding

Breast-feeding is not recommended during administration of Nebilong- AM. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines: No studies on the effects on the ability to drive and use machines have been performed.

This medicine may cause dizziness or fainting as a result to reduction in blood pressure. If these occur, Do not drives or operate machinery. These effects are more likely to occur after initiation of the treatment or after dose increases.

This medicine contains lactose: Patients with rare hereditary problems of galactose intolerance, the Lapp-lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

3. HOW TO TAKE NEBILONG- AM

Always take Nebivolol-AM exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to take

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

The recommended dosage is one tablet of Nebilong-AM once daily. In elderly patients and in patients with renal insufficiency, the recommended starting dose is half tablet of Nebilong- AM once daily, which may be increased to one tablet once daily.

Adolescents and children

Since there are no studies on nebivolol in adolescents and children, this combination is not recommended in these populations.

How long to take it

Your doctor will advise you how long to take your medicine. Your condition may return if you stop using your medicine before you are advised.

If you take more Nebilong- AM than you should (overdose),

If you accidentally take too many tablets (overdose), you may experience slow heart beat, low blood pressure or other heart problems, or difficulty in breathing or wheezing. Contact your nearest hospital casualty department or tell your doctor or pharmacist immediately.

If you forget to take Nebilong- AM

If you forget to take your medicine, but remember to take it after a short time, take the next tablet normally, when it is the time to take it. However, if a long delay has occurred (e.g. all day) skip that dose and take the next dose the next day at the usual time and skip the forgotten dose. Do not take a double or a larger dose to make up with a forgotten dose (s). Repeated skipping is to be avoided.

If you stop taking Nebilong- AM

Always consult your doctor before stopping Nebilong- AM treatment.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Nebivolol can cause side effects, although not everybody gets them.

Common side effects (estimated frequency is less than 1 person out of 10 but more than 1 out of 100) when used for raised blood pressure:

- Headache
- Dizziness
- Tiredness

- An unusual itching or tingling feeling
- Diarrhoea
- Constipation
- Nausea
- Shortness of breath
- Swollen hands or feet

Uncommon side effects (estimated frequency is less than 1 person out of 100 but more than 1 out of 1000) when used for raised blood pressure:

- Slow heartbeat or other heart complaints
- Low blood pressure
- Abnormal vision
- Impotence (difficulty in getting an erection)
- Depressive feelings
- Indigestion, gas in stomach or bowel
- Vomiting
- Skin rash
- Tightening of the chest, difficulty in breathing or wheezing.
- Nightmares
- In a clinical study for chronic heart failure, the side effects seen were slow heart beat, dizziness, worsening of heart failure, low blood pressure (such as feeling faint when getting up quickly), inability to tolerate medicine, irregular heart beat, swelling (such as swollen ankles).

Very rare side effects (estimated frequency is less than 1 person out of 10000):

- Fainting
- Psoriasis aggravated

Like all medicines, Amlodipine can cause side effects, although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.

-Sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).

The following Common side-effects have been reported. If any of these cause problems or if they last more than a week, you should contact your doctor.

Common side effects

- Headache, dizziness, sleepiness
- Palpitations (awareness of your heart beat), flushing
- Abdominal pain, feeling sick (nausea)
- Ankle swelling (oedema), tiredness

Other side-effects that have been reported include the following list. If any of these get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Uncommon side effects

- Mood changes, sleeplessness
- Trembling, taste abnormalities, fainting, weakness
- Visual disturbances, ringing in the ears
- Low blood pressure
- Shortness of breath, sneezing/running nose
- Altered bowel habit, indigestion, dry mouth, vomiting (being sick)
- Hair loss, increased sweating, itchy skin, red patches on skin
- Increased need to urinate especially at night, inability to obtain an erection
- Chest pain, weakness, pain, feeling unwell

-Joint or muscle pain, muscle cramps, back pain

-Weight increase or decrease

-Enlargement of male breasts.

Very rare side effects reported

-Unusual bruising and bleeding (red blood cell damage)

-Severe skin reaction

-Excess sugar in blood (diabetes)

-Increased sensitivity of the skin, pins and needles, loss of pain sensation

-Heart attack

-Hives

-Abdominal bloating (gastritis); Cough; Inflamed pancreas

-Abnormal liver function, inflammation of the liver, yellowing of the skin (jaundice), liver enzyme increases

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 NEBILONG- AM

Keep out of the reach and sight of children.

Store below 30°C.

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

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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Nebilong-AM contains,

Active ingredients: Nebivolol Hydrochloride; Amlodipine Besilate

In active ingredients: Lactose; Microcrystalline cellulose; Betadex (Betacyclodextrin); Cross carmellose (Primellose); Lake of Quinoline Yellow; Dioctyl Sodium sulphate succinate; Povidone (PVP); Crosscarmellose sodium; Colloidal silicon dioxide; Talc; Magnesium Stearate

What Nebilong-AM looks like and contents of the pack

White and Yellow coloured, circular, flat, bevel edged uncoated, bilayered tablets with breakline on one surface

Aluminium/Aluminium Blister Pack of 10 tablets

Manufacturer

MICRO LABS LIMITED

92, SIPCOT,

HOSUR-635 126, INDIA

Marketing Authorisation Holder

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