SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

NEBIGOOD AM

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5mg Nebivolol Hydrochloride eq. to Nebivolol and 5mg Amlodipine
Besylate eq. to Amlodipine

3. PHARMACEUTICAL FORM

Tablet
White, round, flat, beveled uncoated tablets having breakline on one side & plain on other side

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nebivolol 5 mg & Amlodipine 5 mg Tablets is a medicine used to treat hypertension (high blood pressure). This combination medicine controls blood pressure when a single medication is not effective. By lowering the blood pressure, it helps in preventing future heart attack and stroke.

4.2 Posology method of administration

Posology:

Adults: The dose is 5 mg (one tablet) daily, preferably at the same time of the day.
The blood pressure lowering effect becomes evident after 1-2 weeks of treatment.
Occasionally, the optimal effect is reached only after 4 weeks.
Patients with hepatic insufficiency
Data in patients with hepatic insufficiency or impaired liver function are limited, Therefore the use in these patients is contra-indicated.
Paediatric population: Nebivolol 5 mg & Amlodipine 5 mg Tablets is not recommended for use in children and adolescents below 18 years of age due to lack of data on safety and efficacy.
Method Of Administration:
For oral use only

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients. - Liver insufficiency or liver function impairment.

- Acute heart failure, cardiogenic shock or episodes of heart failure decompensation requiring i.v. inotropic therapy.
- sick sinus syndrome, including sino-atrial block.
- second- and third-degree AV-block (without a pacemaker).
- history of bronchial asthma or chronic obstructive pulmonary disease.

- untreated phaeochromocytoma.
- metabolic acidosis.
- bradycardia (heart rate < 60 bpm prior to start therapy).
- hypotension (systolic blood pressure < 90 mmHg).
- severe peripheral circulatory disturbances.

4.4 Special warnings and precautions for use

Drug-Disease Interaction: Nebivolol 5 mg & Amlodipine 5 mg Tablets may have interactions with diabetes, liver impairment, high cholesterol, hyperthyroidism, psoriasis, kidney impairment, asthma, heart problems such as bradyarrhythmia, cardiogenic shock, low blood pressure, fast heart rate, ischemic heart disease, and congestive heart failure.

- Alcohol: It is not recommended not to consume alcohol along with Nebivolol 5 mg & Amlodipine 5 mg Tablets to avoid unpleasant side-effects.
- Regularly monitor blood pressure levels to prevent hypotension (low blood pressure).

Other

Patients with a history of psoriasis should take beta-adrenergic antagonists only after careful consideration.

Beta-adrenergic antagonists may increase the sensitivity to allergens and the severity of anaphylactic reactions.

Beta-blockers may rarely cause decreased lacrimation.

The initiation of Chronic Heart Failure treatment with nebivolol necessitates regular monitoring. For the posology and method of administration.

Treatment discontinuation should not be done abruptly unless clearly indicated.

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

4.5 Interaction with other medicinal products and other forms of interaction

All drugs interact differently for person to person. You should check all the possible interactions with your doctor before starting any medicine.

Interaction with Medicine

Diltiazem: Severe

Fluoxetine: Moderate

Itraconazole: Severe

Amiodarone: Moderate

Rifampicin: Severe

Aminophylline: Severe Disease interactions

Asthma: NebiGood AM Tablet should be used with caution if you have asthma as this medicine may worsen the condition.

Diabetes: NebiGood AM Tablet should be used with caution you have Diabetes mellitus due to the increased risk of altered blood glucose levels.

Glaucoma: NebiGood AM Tablet should be used with caution if you have glaucoma (angle-closer glaucoma). Symptoms include acute onset of decreased visual acuity or ocular pain and typically occur within hours to weeks of drug initiation.
Food interactions: Consumption of grapefruit juice is not recommended during treatment with NebiGood AM Tablet due to the increased risk of hypotension (low blood pressure). You may experience dizziness, headache, swelling of hands and feet, etc.

4.6 Fertility, pregnancy and lactation

Pregnancy
Pregnancy: Nebivolol 5 mg & Amlodipine 5 mg Tablets may be unsafe to use during pregnancy. Although there are limited studies in humans, animal studies have shown harmful effects on the developing baby.
Breast-feeding: Nebivolol 5 mg & Amlodipine 5 mg Tablets is probably unsafe to use during breastfeeding. Limited human data suggests that the drug may pass into the breastmilk and harm the baby.

4.7 Effects on ability to drive and use machines

Not Known

4.8 Undesirable effects

Nervous system disorders
Common: Dizziness
Uncommon: Orthostatic dizziness Not known: Headache Renal and urinary disorders:
Common: Abnormal urination Not known: Impaired renal function.
Gastrointestinal disorders
Common: Nausea/vomiting
Uncommon: Diarrhoea
Not known: Dysgeusia, dyspepsia General disorders and administration site conditions: Common: Fatigue

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important as it allows continued monitoring of the benefit–risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions to the marketing authorisation holder or, where applicable, via the national reporting system.

4.9 Overdose

Symptoms: Symptoms of overdose with beta-blockers are: bradycardia, hypotension, bronchospasm and acute cardiac insufficiency.

Treatment: Blood glucose levels should be checked. Absorption of any drug residues still present in the gastro-intestinal tract can be prevented by

gastric lavage and the administration of activated charcoal and a laxative. Artificial respiration may be required. Bradycardia or extensive vagal reactions should be treated by administering atropine or methylatropine. Hypotension and shock should be treated with plasma/plasma substitutes and, if necessary, catecholamines. The beta- blocking effect can be counteracted by slow intravenous administration of isoprenaline hydrochloride, starting with a dose of approximately 5 mg/minute, or dobutamine, starting with a dose of 2.5 mg/minute, until the required effect has been obtained. In refractory cases isoprenaline can be combined with dopamine. If this does not produce the desired effect either, intravenous administration of glucagon 50-100mg/kg intravenous may be considered. If required, the injection should be repeated within one hour, to be followed -if required- by an intravenous infusion of glucagon 70 µg/kg/h. In extreme cases of treatment-resistant bradycardia, a pacemaker may be inserted.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Nebivolol Hydrochloride

Pharmacotherapeutic group: Beta blocking agent, selective. **ATC code:** C07AB12

Nebivolol is a racemate of two enantiomers, SRRR-nebivolol (or d-nebivolol) and RSSS-nebivolol (or l- nebivolol). It is a competitive and selective beta-receptor antagonist, due to the SRRR-enatiomer (d- enantiomer), and also it has mild vasodilating properties due to an interaction with the L-arginine/nitric oxide pathway.

Amlodipine Besylate

Pharmacotherapeutic group: Calcium channel blockers, selective calcium channel blockers with mainly vascular effects;

ATC code: C 08 CA 01

Amlodipine is a calcium ion influx inhibitor of the dihydropyridine group (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle.

5.2 Pharmacokinetic properties

Nebivolol

Both nebivolol enantiomers are rapidly absorbed after oral administration. The absorption of nebivolol is not affected by food. It can be given with or without meals.

Nebivolol is extensively metabolised, partly to active hydroxy-metabolites. Nebivolol is metabolised via alicyclic and aromatic hydroxylation, N-dealkylation and glucuronidation. In addition, glucuronides of the hydroxy-metabolites are formed. The metabolism of nebivolol by aromatic hydroxylation is subject to the CYP2D6 dependent genetic oxidative

polymorphism. The oral bioavailability of nebivolol averages 12% in fast metabolizing patients and is virtually complete in slow metabolisers.

Amlodipine

Absorption, distribution, plasma protein binding: After oral administration of therapeutic doses, amlodipine is well absorbed with peak blood levels between 6-12 hours post dose. Absolute bioavailability has been estimated to be between 64 and 80%. The volume of distribution is approximately 21 l/kg. In vitro studies have shown that approximately 97.5% of circulating amlodipine is bound to plasma proteins.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of genotoxicity, reproductive and developmental toxicity and carcinogenic potential. Adverse effects on the reproductive function were only recorded at high doses, exceeding by several fold the maximum recommended human dose.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch
Lactose
Microcrystalline Cellulose
Povidone K 30
Purified water
Purified talc
Magnesium Stearate
Colloidal anhydrous silica
Croscarmellose sodium

6.2 Incompatibilities

Not Known

6.3 Shelf life

36 Months

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

10 tablets are packed in ALU-ALU blister, such 3 blisters are packed in one carton with insert coded with batch number, manufacturing date and expiry date.

6.6 Special precautions for disposal and other handling

None

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

Marketing Authorisation Holder:

ZAIN PHARMA LTD.
Plot No: 209/13741, Colchester Park,
Go-Down No.1, 2, 3, Off Mombasa Road,
Behind Nice and Lovely House,
P.O. Box: 100167-00101, Nairobi, Kenya

8. MARKETING AUTHORIZATION NUMBER

H2026/CTD11871/25344

9. Date of First Registration/ Renewal of The Registration

18/02/2026

10. Date of Revision of the Text

18/02/2026