Package leaflet: Information for the user

Nebimel 5 mg Tablets

Nebivolol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nebimel is and what it is used for
Nebimel contains nebivolol, 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).
Nebimel is also used to treat stable mild and moderate chronic heart failure in patients aged 70 or over, in addition to other therapies.

2. What you need to know before you take Nebimel
Do not take Nebimel
- if you are allergic to nebivolol 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) or irregular heartbeat (sick sinus syndrome)
  - certain other serious heart rhythm problems (e.g. 2nd and 3rd degree atrioventricular block, sino-atrial block)
  - heart failure, which has just occurred or which has recently become worse, shock caused by worsening of the heart failure (cardiogenic shock) or you are receiving treatment for circulatory shock due to acute heart failure by intravenous drip feed to help your heart work
  - asthma, wheezing or a condition that affects your breathing (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.

Warnings and precautions
Talk to your doctor or pharmacist before taking Nebimel. Especially if you have
- abnormally slow heartbeat
- a type of chest pain due to spontaneously occurring heart cramp called Prinzmetal angina

- untreated chronic heart failure and ischaemic heart disease (restriction in blood supply)
- 1st 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
- 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.
- prolonged breathing problems combined with cough (you know that you suffer from a chronic obstructive pulmonary disease [COPD])
- psoriasis (a skin disease - scaly pink patches) or if you have ever had psoriasis
- to have surgery, always inform your anaesthetist that you are on Nebimel before being anaesthetised.

If you have serious kidney problems do not take Nebimel 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 younger than 18 years, Nebimel is **not** recommended for use in them.

Other medicines and Nebimel
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 Nebimel:
- 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, 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), phenothiazines (also used for vomiting and nausea) e.g. thioridazine
- medicines for depression e.g. tricyclic antidepressants, paroxetine, fluoxetine
- baclofen (used for the treatment of spastic movement), amifostine (used to treat cancer)
- 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

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. cimitedine: you should take Nebimel during a meal and the antacid drug between meals
- insulin or tablets for diabetes. Although nebivolol does not affect glucose level, concomitant use may mask certain symptoms of hypoglycaemia (increased heart beat)

Pregnancy and breast-feeding
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.

Nebimel should not be used during pregnancy, ***unless clearly necessary.***

Nebimel is not recommended for use while breast-feeding.

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

Nebimel contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, **contact your doctor before** taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Nebimel

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

Nebimel may be taken before, during or after the meal, but, alternatively, you can take it without a meal. The tablet is best taken with some water (e.g. one glass of water).

Treatment of raised blood pressure (hypertension)
- the recommended dose is 1 tablet per day. The dose should be taken preferably at the same time of the day
- elderly patients over 65 years and patients with a kidney disorder will usually start with ½ (half) tablet daily. If needed, the daily dose may be increased to 1 tablet
- 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 (10 mg) a day
- you will need to be under the close supervision for at least 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
- take your medicine once daily, preferably at about the same time of day

Patients with serious kidney problems should not take Nebimel, as there is no clinical experience in these patients.

If you have been told by your doctor to take ¼ (quarter) or ½ (half) tablet daily, you will need to break the tablet along the 'score' lines before taking. Nebimel tablets have a cross-score to facilitate the individual dosage. Please refer to the instructions below on how to break Nebimel tablets.
- place the tablet on a hard surface with the centre groove facing upward
- exert pressure from the top with your thumb and the tablet will break into four equal pieces

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

Use in children and adolescents
Do not use Nebimel in children or adolescents younger than 18 years.

If you take more Nebimel 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 Nebimel overdose are very slow heart beat (bradycardia), low blood pressure with possible fainting (hypotension), breathlessness such as in asthma (bronchospasm), and acute heart failure.

If you forget to take Nebimel
If you forget a dose of Nebimel, 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 for a forgotten dose. Repeated skipping, however, should be avoided.

If you stop taking Nebimel
You should always consult with your doctor before stopping Nebimel treatment, whether you are taking it for high blood pressure or chronic heart failure.
You should not stop Nebimel treatment abruptly as this can temporarily make your heart failure worse. If it is necessary to stop Nebimel 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.

4. Possible side effects

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

When Nebimel 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 (paraesthesia)
- diarrhoea
- constipation
- nausea
- shortness of breath
- accumulation of fluid in the body resulting in swelling, particularly of the legs and ankles (oedema).

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 (intermittent claudication)
- 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 (may affect up to 1 in 10,000 people):
- fainting
- worsening of psoriasis (a skin disease - scaly pink patches)

Not known (frequency cannot be estimated from the available data):
- swelling of the lips, eyes or tongue (angioneurotic oedema), with possible sudden difficulty breathing
- allergic reactions
- hives (urticaria)

Other side effects seen with drugs that are similar to nebivolol are: hallucinations, mental disorders and confusion, cold fingers and toes sometimes going pale or blue, dry eyes, and a severe disorder of the eyes and mouth.

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

Very common side effects (may affect more than 1 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 (1st degree AV-block)
- swelling of the lower limbs (such as swollen ankles)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
HPRA Pharmacovigilance, Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nebimel

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

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

Do not store above 30°C.

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.

6. Contents of the pack and other information

What Nebimel contains

- The active substance is nebivolol. Each tablet contains nebivolol hydrochloride equivalent to 5 mg nebivolol.
- The other ingredients are povidone K30, lactose monohydrate, maize starch pregelatinised, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate and crospovidone.

What Nebimel looks like and contents of the pack
There is only one strength of Nebimel. These are white, round, cross-scored tablets and are available in blister packs of 7, 10, 14, 28, 30, 50, 56, 84, 98, 100 and 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary

Manufacturer
STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel, Germany

This medicinal product is authorised in the Member States of the EEA under the following names

Austria:	Nebivolol STADA 5 mg Tabletten
Belgium:	Nebivolol EG 5 mg comprimés
Estonia:	Nebivolol STADA 5 mg tabletid
France:	Nebivolol EG 5 mg, comprimé
Germany:	Nebivolol STADA/AL 5 mg Tabletten
Ireland:	Nebimel 5 mg tablets
Italy:	Nebivololo EG 5 mg compresse
Latvia:	Nebivolol STADA 5 mg tabletes
Lithuania:	Nebivolol STADA 5 mg tablets
Luxembourg:	Nebivolol EG 5 mg comprimés
Portugal:	Nebivolol Ciclum 5 mg comprimidos
The Netherlands:	Nebivolol CF 5 mg, tabletten

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