

PACKAGE LEAFLET

Package leaflet: Information for the user

Nebivolol Accord 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, 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 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 Nebivolol Accord is and what it is used for
2. What you need to know before you take Nebivolol Accord
3. How to take Nebivolol Accord
4. Possible side effects
5. How to store Nebivolol Accord
6. Contents of the pack and other information

1. What Nebivolol Accord are and what they are used for

Nebivolol Accord 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).

Nebivolol Accord is also used to treat 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 Nebivolol Accord

Do not take Nebivolol Accord

- if you are allergic to the active substance nebivolol hydrochloride or any of the other ingredients of this medicine (listed in section 6),
- if you have one or more of the following disorders:
 - liver function disorder
 - 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
 - sick sinus syndrome (a certain type of disturbance in heart rhythm) including sino-arterial block (SA block)
 - certain heart conduction disorders (2nd and 3rd degree heart block – AV block [without pacemaker])
 - asthma or wheezing (now or in the past)
 - untreated pheochromocytoma, a tumour located on top of the kidneys (in the adrenal glands)
 - a metabolic disorder (metabolic acidosis), for example, diabetic ketoacidosis.

- very slow heartbeat (less than 60 beats per minute)
- low blood pressure
- serious circulation problems in the arms or legs

Warnings and precautions

Talk to your doctor or pharmacist before taking Nebivolol Accord

Inform your doctor if you have or develop one of the following problems:

- abnormally slow heartbeat
- a type of chest pain due to spontaneously occurring heart cramp called Prinzmetal angina
- untreated chronic heart failure
- 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
- prolonged breathing problems
- 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
- 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 Nebivolol Accord before being anaesthetised.

If you have serious kidney problems do not take Nebivolol 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, Nebivolol Accord is **not** recommended for use in them.

Other medicines and Nebivolol Accord

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

Always tell your doctor if you are using or receiving any of the following medicines in addition to Nebivolol Accord:

- 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), phenothiazine (also used for vomiting and nausea), levomepromazin, and thioridazine.
- Medicines for depression e.g. amitriptyline, paroxetine, fluoxetine, bupropion.
- 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)
- Chloroquine (medicine used to treat malaria)
- terbinafine (a medicine used to treat fungal infections)

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 Accord during a meal and the antacid drug between meals.

Nebivolol Accord with food and drink

Please refer to section 3.

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 any medicine.

Pregnancy

Nebivolol Accord should not be used during pregnancy, unless clearly necessary.

Breast-feeding

It 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.

Nebivolol Accord 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 Nebivolol Accord

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

Nebivolol Accord may be taken before, during or after the meal, but, alternatively, you can take it independently of meals. The tablet is best taken with some water.

Treatment of raised blood pressure (hypertension)

- The recommended dose is 5 mg of nebivolol once a day. The dose should be taken preferably at the same time of the day.
- Older patients and patients with a kidney disorder will usually start with 2.5 mg of nebivolol 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 1.25 mg per day. This may be increased after 1-2 weeks to 2.5 mg per day, then to 5 mg per day and then to 2 tablets (10 mg) 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 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.

If you have been told by your doctor to take $\frac{1}{4}$ or $\frac{1}{2}$ (two quarters) tablet, place the tablet onto a flat, hard surface, such as a table, with the score facing up.

Press evenly on the entire tablet surface until a snapping sound is heard.

The tablet has now been divided into 4 parts which can be carefully separated.

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

Do not use in children or adolescents.

If you take more Nebivolol Accord 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 Accord 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 Nebivolol Accord

If you forget a dose of Nebivolol Accord, 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 Nebivolol Accord

You should always consult with your doctor before stopping Nebivolol Accord 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.

4. Possible side effects

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

Stop taking Nebivolol Accord and seek medical help immediately if you have any of the following reactions:

Swelling of the face, lips, tongue and/or throat, which may cause difficulty in breathing and swallowing (angioedema), severe itching of the skin (with raised lumps). *Frequency not known (cannot be estimated from the available data)*

When Nebivolol Accord 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
- unusual itching or tingling feeling
- shortness of breath
- constipation
- nausea
- diarrhoea
- tiredness
- swollen hands or feet

Uncommon side effects (may affect up to 1 in 100 people)

- nightmares
- feelings of depression
- abnormal vision
- slow heartbeat or other heart complaints
- conduction defects in the heart
- low blood pressure
- cramp-like leg pains on walking
- breathlessness such as in asthma, due to sudden cramps in the muscles around the airways (bronchospasm)
- digestive difficulties (dyspepsia), gas in stomach or bowel
- vomiting
- skin rash, itchiness
- impotence

Very rare side effects (may affect up to 1 in 10,000 people)

- fainting (syncope),
- worsening of psoriasis (a skin disease – scaly pink patches)

Not known (frequency cannot be estimated from the available data)

- allergy (hypersensitivity),
- angioneurotic oedema (swelling of face, lips, mouth, tongue or throat)
- urticaria (Itchy rash)

The following side effects have also been reported with similar medicines:

- hallucinations
- psychotic reactions (psychoses)
- confusion
- cold/bluish-red discoloration of the arms and legs
- pain in fingers and toes which first turn bluish, then whitish, and finally reddish (Raynaud's syndrome)
- dry eyes
- formation of new connective tissue in the eyes and the diaphragm (practolol-type oculomucocutaneous toxicity).

*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 Nebivolol Accord

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 blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Nebivolol Accord contains

- The active substance is nebivolol.
Each tablet contains 5.45 mg of nebivolol hydrochloride equivalent to 5 mg of nebivolol.
The other ingredients are silica colloidal hydrated (E551), magnesium stearate (E572), croscarmellose sodium (E468), macrogol (E1521) and lactose

What Nebivolol Accord looks like and contents of the pack

Tablet

Round, white, convex, approximately 9 mm in diameter cross-scored tablets (snap-tab cross-score), marked with 'NE3' on other side.

Clear PVC/PE/PVdC ultrasafe Aluminium blisters and PVC/PVDC Aluminium blisters are available in 14, 28, 30, 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Netherlands	Nebivolol Accord 2.5/5 mg tabletten
Austria	Nebivolol Accord 5 mg tabletten
Denmark	Nebivolol Accord
Finland	Nebivolol Accord 5 mg tabletti
Ireland	Nebivolol Accord 5 mg tablets
Cyprus	Nebivolol Accord 2.5/5 mg tablets
Italy	Nebivololo Accord

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