

Package leaflet: Information for the patient

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

1. What Nebol is and what it is used for

Nebol 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 to as well lower blood pressure.

It is used to treat raised blood pressure (hypertension).

Nebol 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 Nebol

Do not take Nebol

- if you are allergic (hypersensitive) 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)
 - certain other serious heart rhythm problems (e.g. 2nd and 3rd degree atrioventricular block, heart conduction disorders)
 - 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
 - asthma or wheezing (now or in the past)
 - untreated pheochromocytoma, 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 Nebol 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 Nebol before being anaesthetised.

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

Other medicines and Nebol

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, **including** medicines obtained without a prescription. 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 Nebol:

- 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, nifedipine, nifedipine, nimodipine, nitrendipine, propafenone, quinidine, rilmenidine, verapamil)
- sympathicomimetic agents (drugs that mimic the effects of sympathetic activation on the heart and circulation)
- sedatives and therapies for psychosis (a mental illness) e.g. barbiturates (also used for epilepsy), phenothiazine (also used for vomiting and nausea) and thioridazine)
- medicines for depression e.g. amitriptyline, paroxetine, fluoxetine
- 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

- amifostine used during cancer treatment
- baclofen used to treat epilepsy.

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 Nebol during a meal and the antacid drug between meals.

Nebol with food and drink

Nebivolol can be taken with food or on an empty stomach, but the tablet is best taken with some water.

Pregnancy and breast-feeding

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

It is not recommended for use while 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.

Driving or using machines

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

Nebol contains lactose and sodium

This medicine contains lactose. 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 Nebol

Always take Nebol exactly as your doctor has told you. You should check with your doctor if you are not sure.

Nebol 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 usual dose is 1 tablet per day. The dose should be taken preferably at the same time of the day.
- Elderly patients and patients with a kidney disorder will usually start with ½ (half) tablet 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 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 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.

Tablet dividing instructions

If you have been told by your doctor to take ¼ or ½ (two quarters) tablet, proceed as follows:

1. Place one tablet on a smooth and hard surface in such a way that the four-leaf clover is on the upper face of the tablet and tablet scores coincide with 12 o'clock and 3 o'clock and 6 o'clock and 9 o'clock directions (Figure 1).

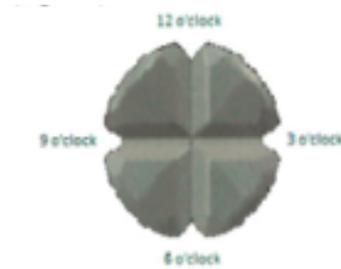


Figure 1 - Direction of tablets

2. Place your thumb on the tablet surface so that your thumb coincides with 3 o'clock to 9 o'clock direction (Figure 2).

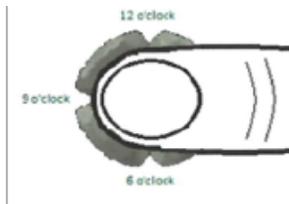


Figure 2 - Placement of thumb

3. Apply a uniform pressure to the tablet surface until the tablet breaks.

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

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

Do not use in children or adolescents.

If you take more Nebol 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 Nebol overdose are very slow heartbeat (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 Nebol

If you forget a dose of Nebol, 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. Repeated skipping, however, should be avoided.

If you stop taking Nebol

You should always consult with your doctor before stopping Nebol treatment, whether you are taking it for high blood pressure or chronic heart failure.

You should not stop Nebol treatment abruptly as this can temporarily make your heart failure worse. If it is necessary to stop Nebol 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 product, ask your doctor or pharmacist.

4. Possible side effects

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

When Nebol 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
- diarrhoea
- constipation
- nausea
- shortness of breath
- swollen hands or feet.

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
- 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 10000 people):

- fainting
- worsening of psoriasis (a skin disease - scaly pink patches).

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

- 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
- psychoses
- confusion
- cold extremities, cyanotic extremities (blue or purple colouration of the skin)
- Raynaud phenomenon (discolouration of the fingers, toes, and occasionally other areas)
- dry eyes
- formation of new connective tissue in the eyes and the diaphragm (practolol-type oculo-mucocutaneous toxicity).

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

Very common side effects (may affect more than 1 in 10 people):

- slow heartbeat
- 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 Nebol

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 blister and carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Shelf life after first opening:

Bottle: 6 months

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 Nebol contains

- The active substance is nebivolol. Each tablet contains 5 mg nebivolol equivalent to 5.45 mg of nebivolol hydrochloride.
- The other ingredients are croscarmellose sodium, lactose monohydrate, maize starch, cellulose microcrystalline, hypromellose 5 cps, silica colloidal anhydrous, magnesium stearate.

What Nebol looks like and contents of the pack

White or almost white, four-leaf clover shape on one-side, convex on other-side, quadrisect shape on both sides, snap tablets (diameter 9 mm).

The tablets are packed in PVC/aluminium blisters or polyethylene bottles and inserted in a carton.

Pack sizes:

B blister: 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100, 500 tablets

Bottle: 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100, 500 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Lek S.A., ul. Domaniewska 50C, 02-672, Warszawa, Poland.

Lek Pharmaceuticals d.d., Verovškova 57, 1526, Ljubljana, Slovenia.

Lek S.A., 16 Podlipie Str., 95-010 Stryków, Poland.

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

Estonia: Nebicard 5mg

Germany: Nebivolol HEXAL 5 mg Tabletten

Hungary: Nebivolol Sandoz 5 mg tableta

Ireland: Nebol 5 mg tablets

Italy: Nebivololo Aristo 5 mg compresse

Lithuania: Nebicard 5mg tabletės

This leaflet was last revised in 03/2020.