

PACKAGE LEAFLET

Package leaflet: Information for the patient

Nelet 5 mg Tablets

nebivolol

Read all of this leaflet carefully before you start taking this medicine because it might contain 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 Nelet is and what it is used for
2. What you need to know before you take Nelet
3. How to take Nelet
4. Possible side effects
5. How to store Nelet
6. Contents of the pack and other information

1. What Nelet is and what it is used for

Nelet belongs to a group of medicines called beta-blockers that are used to lower blood pressure. Nelet is used to treat:

- high blood pressure (hypertension)
- elderly patients suffering from mild to moderate heart failure in addition to standard therapy (e.g. with diuretics, digoxin, ACE inhibitors, angiotensin II antagonists).

2. What you need to know before you take Nelet

Do not take Nelet if you

- are allergic to nebivolol or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, swelling or difficulty breathing
- have liver problems
- have had a heart attack, have heart failure which might be getting worse or have had intravenous medical treatment for heart failure.
- have missed heart beats (conditions such as sick sinus syndrome, sinoatrial block or second or third degree heart block) but have not been fitted with a pacemaker
- have or have had asthma or other serious breathing problems
- have a tumour of the adrenal gland called a phaeochromocytoma that is not being treated
- have a condition called metabolic acidosis
- suffer from a slow heart beat (fewer than 60 beats per minute, known as bradycardia)
- suffer from low blood pressure or have very poor circulation
- use medicines containing floctafenine or sultopride

Warnings and precautions

Talk to your doctor or pharmacist before taking Nelet if you:

- have ongoing heart problems that are not being treated as Nelet may make these worse.

- have Raynaud's disease, poor circulation in the arms or legs or have periods when walking is difficult, including bouts of limping or lameness, as Nelet may make these conditions worse.
- have been told by a doctor that you have a first degree heart block (missed heart beats) as Nelet may make this worse or slow down your heart rate. Your doctor may want to monitor your heart rate and if necessary change your dosage.
- suffer from Prinzmetal's angina as Nelet may make your angina attacks worse.
- are diabetic as Nelet may mask some of the signs that your blood sugar levels are low (hypoglycaemia).
- have an over active thyroid gland (hyperthyroidism) as Nelet may mask some of the signs of this condition such as a fast heart rate (tachycardia).
- have problems with your lungs as Nelet can cause further breathing difficulties. Your doctor will advise you if you are at risk.
- have a skin condition called psoriasis or if you suffer from hay fever or have other allergies because Nelet may make these conditions worse. Talk to your doctor if you are unsure about whether to take this medication.
- wear contact lenses, as Nelet may cause dry eyes.

Other medicines and Nelet

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription or the following.

Do not take Nelet if you are taking any medicines containing floctafenine or sultopride (see section 'Do not take' above).

Taking any of these medicines and Nelet may lower your blood pressure too much or cause heart problems

- medicines to lower your blood pressure such as verapamil, diltiazem, clonidine, guanfacin, moxonidine, methyldopa, rilmenidine, amlodipine, felodipine, lacidipine, nifedipine, nicardipine, nimodipine, nitrendipine
- medicines to treat abnormal heart rhythms such as amiodarone, quinidine, hydroquinidine, cibenzoline, flecainide, disopyramide, lidocaine, mexiletine, propafenone
- medicines to treat depression or other mental problems such as paroxetine, fluoxetine, thioridazine
- barbiturates (used for epilepsy, anxiety or insomnia)
- baclofen (a muscle relaxant)
- amifostine (used in cancer therapy)
- Mefloquine (antimalarian drug)
- Organic nitrates (to treat chest pain)
- Quinidine (used to slow down the heart)
- Terbinafine (for fungal or yeast infections)
- Bupropion (to help in cessation of smoking)
- Chloroquine (for malaria or rheumatoid arthritis)
- Levomepromazine (for mental health problems)

Also:

- stimulants containing dopamine or decongestants containing ephedrine, as they may increase your blood pressure too much or cause heart problems.
- insulin or any oral anti-diabetic medicines because Nelet may mask symptoms of hypoglycaemia (low sugar level of the blood) like a racing heart beat or palpitations

Surgery

Nelet may react with certain anaesthetics used in operations. So in the event that you need any form of surgery, you should tell your doctor, dentist or the medical staff at the hospital that you are taking Nelet.

Pregnancy and breast-feeding

Nelet should not be given to pregnant or breast-feeding mothers unless the benefits to the mother outweigh the risks to the baby.

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 and using machines

This medicine may cause dizziness or fainting as a result of a reduction in blood pressure. If these occur, do not drive or operate machinery. These effects are more likely to occur at the start of the treatment or after dose increases (see also section 4).

Nelet contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. How to take Nelet

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

Always check that you have enough tablets and do not run out. Try to take your tablets at the same time each day. Swallow the tablet with a glass of water. You may take your tablets with or without food.

The tablet can be divided into 4 equal doses.

Treatment for high blood pressure:

Use in adults: The usual dose is 5 mg of Nelet once a day. It usually takes 1 – 2 weeks for the medicine to work but occasionally it may take up to 4 weeks.

Elderly: If you are over 65 years and taking Nelet to lower your blood pressure the usual starting dose is 2.5 mg per day. However, your doctor may increase this to 5 mg per day if they feel this is necessary.

Patients with kidney disease: The usual dose is 2.5 mg once a day. However, your doctor may increase your dose to 5 mg per day if required.

Patients taking Nelet and another medicine to lower your blood pressure:

When taken with hydrochlorothiazide the usual daily dose is 5 mg of Nelet and 12.5 – 25 mg of hydrochlorothiazide per day.

Treatment for heart failure:

Use in adults and the elderly: Your doctor will start you on a low dose and gradually increase your dose over 1 – 2 weekly intervals until your condition has stabilised. The usual starting dose is 1.25 mg once daily for 1 – 2 weeks, this may be increased to 2.5 mg once daily, then to 5 mg once daily and then to 10 mg once daily. The maximum recommended dose is 10 mg once daily. Your doctor will tell you how much to take.

Patients with kidney disease:

Nelet is not recommended for use in patients with severe kidney disease. Your doctor will advise you whether Nelet is suitable for your condition.

Patients with liver disease:

If you suffer from liver disease **do not** take Nelet.

Use in children and adolescents:

Nelet is not recommended for use in children or adolescents below 18 years.

If you take more Nelet than you should

Contact your doctor or casualty department immediately. Take the container and any remaining tablets with you. Signs and symptoms of overdose include: a slow heart rate, low blood pressure, wheezing and difficulty breathing and sudden heart problems.

If you forget to take Nelet

If you forget to take a dose of Nelet **do not** take a double dose to make up for a forgotten dose. Take the next dose on time. If you miss several doses contact your doctor.

If you stop taking Nelet

If you suddenly stop taking Nelet you are likely to suffer from side effects, or your illness may get worse. If you need to stop taking this medicine your doctor will reduce your dose slowly over a 2 week period.

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.

If any of the following happen, stop taking Nelet and tell your doctor immediately or go to your nearest hospital emergency department:

- tightness of the chest and difficulty breathing.
- serious allergic reactions which may cause a rash, itching, hives or swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- heart failure which may cause shortness of breath, getting tired easily after light physical activity or swelling of the feet or legs due to fluid build up
- changes in the electrical activity of your heart causing missed heart beats
- problems with your eye such as inflammation, dryness of the eye, redness or gritty-irritation of the eyelid which may cause damage to the eye
- mental health problems (psychoses) which may cause you to hear, see or feel things that aren't there (hallucinations), have false beliefs (delusions), be confused, have disturbed or unusual thoughts or behaviour

Other possible side effects include:

Common side effects (may affect up to 1 in 10 people):

- headaches
- tingling or pins and needles
- fainting on standing up
- constipation, feeling sick (nausea) or diarrhoea
- feeling tired
- fluid retention (swelling)
- shortness of breath

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

- nightmares
- feelings of depression
- problems with eyesight
- slow heartbeat or other heart complaints
- other changes in how your heart works, which can be seen during heart exams
- low blood pressure

- difficulty or pain walking including muscle cramps, limping or lameness
- breathlessness such as in asthma, due to sudden cramps in the muscles around the airways (bronchospasm)
- indigestion, flatulence (passing wind), being sick (vomiting)
- inability to get or maintain an erection
- skin rash, skin itchiness

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

- fainting
- worsening of your psoriasis, or skin rash psoriasis-like (thickened patches of red skin, often with silvery scales)

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

- whole-body allergic reactions, with generalised skin eruption (hypersensitivity reactions);
- rapid-onset swelling, especially around the lips, eyes, or of the tongue with possible sudden difficulty breathing (angioedema);
- kind of skin rash notable for pale red, raised, itchy bumps of allergic or non allergic causes (urticaria).

The following side effects have been reported with medicines of the same type as nebivolol, so may be seen with this medicine. **The frequency cannot be estimated from the available data.**

- cold fingers and toes with bluish discolouration of the skin (Raynaud's phenomenon)
- dry eyes

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):

- dizziness
- slow heart rate

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)
- intolerance to Nelet
- 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 side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nelet

Keep 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 or bottle label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice any discolouration of the tablets.

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 Nelet 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 lactose monohydrate (see section 2 'Nelet contains lactose'), croscarmellose sodium, maize starch, polysorbate 80, hypromellose, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate.

What Nelet look like and contents of the pack

Nelet Tablets are white, rectangular, flat-faced, bevelled-edged tablets with 3 breaklines on each side. Each tablet is marked "N", "L" "5" on one side only.

This medicine is available in aluminium/aluminium foil blisters in packs of 7, 10, 14, 28, 30, 50, 56, 60, 84, 90, 98 and 100 tablets, in opaque plastic bottles containing 100 or 500 tablets or in aluminium/aluminium perforated unit dose blisters in pack sizes of 28 x 1, 56 x 1, 100 x 1 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturer

McDermott Laboratories Limited t/a Gerard laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft,
H-2900 Komárom,
Mylan utca 1,
Hungary

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

Austria	Nebivolol Arcana 5 mg Tabletten
Belgium	Nebivolol Mylan 5 mg tabletten
France	Nebivolol Mylan 5 mg comprimé quadrisécable
Greece	Nebivolol/Generics 5 mg Tablets
Hungary	Nebivogen 5 mg tabletta
Ireland	Nelet 5 mg Tablets
Italy	NIVOLON 5 mg compresse
Portugal	Nebivolol Mylan 5 mg comprimidos
Spain	Nebivolol Mylan 5 mg comprimidos EFG
The Netherlands	Nebivolol Mylan 5 mg tabletten
United Kingdom	Nebivolol 5 mg Tablets

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