
D4 Patient Information Leaflet (PIL)

NODON (Nebivolol Tablets 5 mg)

Nebivolol Tablets 5mg

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What Nodon is used for

Nebivolol belongs to a group of medicines called beta-blockers that are used to lower blood pressure. Nebivolol 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).

How Nodon works

Nebivolol works by relaxing blood vessels and slowing heart rate to improve blood flow and decrease blood pressure.

Before you take Nodon

– Do not take Nodon if you

- are allergic to nebivolol or any of the other ingredients of this medicine
- 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 pheochromocytoma 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

Before you take it

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

- have ongoing heart problems that are not being treated as Nebivolol 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 Nebivolol may make these conditions worse.
- have been told by a doctor that you have a first degree heart block (missed heart beats) as Nebivolol 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 Nebivolol may make your angina attacks worse.
- are diabetic as Nebivolol may mask some of the signs that your blood sugar levels are low (hypoglycaemia).
- have an over active thyroid gland (hyperthyroidism) as Nebivolol may mask some of the signs of this condition such as a fast heart rate (tachycardia).
- have problems with your lungs as Nebivolol 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 Nebivolol may make these conditions worse. Talk to your doctor if you are unsure about whether to take this medication.
- wear contact lenses, as Nebivolol may cause dry eyes.

Taking other medicines

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.

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

- medicines to lower your blood pressure such as verapamil, diltiazem, clonidine, guanfacin, moxonidine, methyl dopa, 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 (antimalarial drug): Theoretically co-administration with β (beta) -adrenergic blocking agents might contribute to a prolongation of the QTc interval.

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- Organic nitrates (to treat chest pain)
- Quinidine (used to slowdown 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 Nebivolol may mask symptoms of hypoglycaemia (low sugar level of the blood) like a racing heart beat or palpitations

How to take Nodon

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

– When to take it

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.

– How much to take

Take *Nodon* as directed by your doctor. Your doctor will tell you how much *Nodon* you need to take each day. Do not take more than the recommended dose.

The tablet can be divided into 4 equal doses.

Treatment for high blood pressure:

Adults: The usual dose is 5 mg of Nebivolol 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 Nebivolol 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 Nebivolol and another medicine to lower your blood pressure:

When taken with hydrochlorothiazide the usual daily dose is 5 mg of Nebivolol 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.

– If you take too much (overdose)

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 it

If you forget to take a dose of Nebivolol 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 Nebivolol

If you suddenly stop taking Nebivolol 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 taking this medicine, ask your doctor or pharmacist.

4. While you are using it

– Things you must do

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 Nodon

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.

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.

– Things you must not do

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.

Patients with kidney disease:

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

Patients with liver disease:

If you suffer from liver disease do not take Nebivolol.

Use in children and adolescents:

Nebivolol is not recommended for children or adolescents below 18 years.

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– Things to be careful of

If any of the following happen, stop taking Nodon 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 buildup
- 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 behavior

Side Effects

Common side effects

- 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

- nightmares
- feelings of depression
- problems with eye sight
- 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

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

Not known

- 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.

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

For chronic heart failure, the following side effects were seen:

Very common side effects

- dizziness
- slow heart rate

Common side effects

- worsening of heart failure
- low blood pressure (such as feeling faint when getting up quickly)

- intolerance to Nebivolol
- a kind of light heart conduction disorder that affects heart rhythm (1st degree AV-block)
- swelling of the lower limbs (such as swollen ankles).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Nodon

– Storage

Store below 30°C. Protect from light.

Keep out of the sight and reach of children.

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

– Disposal

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.

Product Description

– What it looks like

White to off-white, round, uncoated tablets with cross breakline on both the side.

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– **Ingredients**

The active substance is nebivolol Hydrochloride.

Each tablet contains 5.45 mg of nebivolol hydrochloride equivalent to 5 mg of nebivolol.

The other ingredients are lactose monohydrate, Pre- gelatinized starch, hydroxypropylmethyl cellulose, Polysorbate 80, Microcrystalline Cellulose, Croscarmellose Sodium, Colloidal Anhydrous Silica & Magnesium Stearate

This medicine is available in Alu/PVC blisters of 2x14 Tablets

- **MAL number:**

MAL*****

Manufacturer

Cadila Pharmaceuticals Ltd,
1389, Trasad Road, Dholka–
382225, District: Ahmedabad,
Gujarat State, India.

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai,
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Klang, Selangor, Malaysia.

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