

Package leaflet: Information for the user

Nebinad, 5 mg, tablets Nebivolol

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

1. What Nebinad is and what it is used for

Nebinad 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.

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

It is also used to treat mild and moderate chronic heart failure in patients aged 70 or over, in addition to other therapies.

Nebinad is also used to treat symptomatic stable coronary artery disease.

2. What you need to know before you take Nebinad

Do not take Nebinad:

- 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 (the systolic or “upper” pressure is less than 90 mmHg)
 - serious circulation problems in the arms or legs
 - very slow heartbeat (less than 60 beats per minute before having started this medication)
 - conduction disorders in your heart (such as sick sinus syndrome, including sino-atrial block or 2nd and 3rd degree atrioventricular blockade and you do not have a functioning pacemaker) or if you have acute heart failure, you have experienced cardiogenic shock or you are receiving treatment into a vein (by intravenous ‘drip’) to help your heart work
 - difficulty in breathing or wheezing (now or in the past)
 - severe asthma or chronic obstructive pulmonary disease.
 - 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 (when the blood sugar has risen too much and blood has become too acidic).
- if you use either floctafenine or sultopride containing medicines.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nebinad.

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 (inability of heart to pump enough blood for body's needs)
- 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 mask 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, as Nebinad may aggravate the symptoms

If you have to have surgery or need an anaesthetic, always inform your anaesthetist or dentist that you are on Nebinad before being anaesthetised.

If you have serious kidney problems do not take Nebinad 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).

Nebinad may cause decreased lacrimation. Therefore, inform your doctor if you wear contact lenses.

Children and adolescents

Because of the lack of data on the use of the product in children and adolescents, Nebinad is **not** recommended for use in them.

Other medicines and Nebinad

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

Always tell your doctor or pharmacist if you are using or receiving any of the following medicines in addition to Nebinad as the way nebivolol works or the other medicine works may be affected:

- Medicines to treat heart conditions or high blood pressure (amiodarone, amlodipine, cibenzoline, clonidine, digoxin or other so called digitalis glycosides, diltiazem, disopyramide, felodipine, flecainide, guanfacin, hydroquinidine, lacidipine, lidocaine, methyl dopa, mexiletine, moxonidine, nifedipine, nicardipine, nimodipine, nitrendipine, organic nitrates, propafenone, quinidine, rilmenidine, verapamil –verapamil should not be injected into a vein)
- Medicines for depression or psychoses (e.g. fluoxetine, paroxetine, tricyclic antidepressants, thioridazine, phenothiazines such as levomepromazine)
- Sedative medicines which may be used to treat epilepsy (barbiturates)
- Anti-inflammatory medicines for pain or rheumatism (NSAIDs)
- Diabetic medicines (insulins and oral preparations)
- Medicine for excess acid (cimetidine). You should take Nebinad during a meal, and the antacid drug between meals
- Anaesthetics: always inform your anaesthetist that you are on Nebinad before being anaesthetized
- Muscle relaxant (baclofen)

- Medicine that is taken during chemo- or radiation therapy to protect you (amifostine)
- Anti-fungal or to treat yeast infections (terbinafine)
- Medicine that helps in stopping smoking (bupropion)
- Anti-malarials (mefloquine, chloroquine – which is also used for rheumatism)
- Medicines for asthma or to treat a blocked nose
- Medicine for some eye disorders such as glaucoma (increased pressure in the eye) or dilation of the pupil

Nebinad with food and drink

Nebinad can be taken before, during or after a meal, but also you can take them without food. The tablet or its parts should be swallowed with some water or another liquid.

Pregnancy and breast-feeding

Nebinad should not be used during pregnancy unless instructed to do so by a doctor.

Breast-feeding is not recommended during administration of Nebinad.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

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

Nebinad contains lactose monohydrate

If your doctor has told you that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Nebinad

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

Treatment of raised blood pressure (hypertension)

- The usual dose is 1 tablet (5 mg) 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 tablet (2.5 mg) daily.
- It may take up to 4 weeks for this medicine to have full effect.
- If you are aged over 75 years, your doctor may need to monitor you more closely.

Treatment of chronic heart failure

- Your treatment will be started and monitored by an experienced physician.
- Your doctor will start your treatment with ¼ tablet (1.25 mg) per day. This may be increased after 1-2 weeks to ½ tablet (2.5 mg) per day, then to 1 tablet (5 mg) per day and then to 2 tablets (10 mg) per day until the correct dose is reached for you.
- The maximum recommended dose is 10 mg (2 tablets a day).
- You will need to be monitored 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, and you should not stop abruptly as this can worsen heart failure.
- Patients with serious kidney problems should not take this medicine.

Treatment of symptomatic stable coronary artery disease

- Your treatment will be started and monitored by an experienced physician.

- Your doctor will start your treatment with ¼ tablet per day (1.25 mg). Depending on tolerance to this medicinal product the dose can be increased after 1-2 weeks to ½ tablet per day (2.5 mg), then to 1 tablet (5 mg) per day and then to 2 tablets (10 mg) per day until the correct dose is reached for the patient.
- The maximum recommended dose is 10 mg (2 tablets a day).

If you have liver problems and have been told that your liver does not work properly, you should not take this medicine.

Take your medicine once daily, preferably at about the same time of day.

Your doctor may decide to combine your tablets with other medicine for your condition.

Use in children and adolescents

Nebinad is not recommended in children and adolescents.

If you take more Nebinad than you should

If you accidentally take too many tablets (overdose), you may experience slow heartbeat, low blood pressure or other heart problems, or difficulty in breathing or wheezing. Contact your nearest hospital casualty department or tell your doctor or pharmacist immediately.

If you forget to take Nebinad

If you forget to take your medicine, but remember to take it after a short time, take the next tablet normally, when it is the time to take it. However, if a long delay has occurred (e.g. all day) skip that dose and take the next dose the next day at the usual time and skip the forgotten dose. Do not take a double dose to make up for a forgotten dose (s). Repeated skipping is to be avoided.

If you stop taking Nebinad

Do not stop taking Nebinad without consulting your doctor first. If the medication is terminated abruptly, the patient may experience dangerous worsening of the symptoms. This concerns especially the patients with heart failure

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 Nebinad is used for the treatment of raised blood pressure, the possible side effects are:

Common side effects (more than 1 person in every 100 treated but fewer than 1 person in every 10 treated):

- headache,
- dizziness,
- tiredness,
- paraesthesia (an unusual itching or tingling feeling),
- diarrhoea,
- constipation,
- nausea,
- shortness of breath,
- oedema (swollen hands or feet).

Uncommon side effects (more than 1 person in every 1,000 treated but fewer than 1 person in every 100 treated):

- slow heartbeat, heart failure or other heart complaints,
- low blood pressure,
- cramp-like leg pains on walking,
- abnormal vision,

- impotence (difficulty in getting an erection),
- depressive feelings,
- digestive difficulties (dyspepsia), gas in stomach or bowel,
- vomiting,
- skin rash, itching,
- tightening of the chest, difficulty in breathing or wheezing,
- nightmares.

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

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

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

- angioedema: swelling of the skin of the face or extremities, lips, tongue, mucous membranes of the throat and airway, resulting in shortness of breath or difficulty to swallow – contact a doctor immediately!
- hypersensitivity,
- urticaria.

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

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

- slow heartbeat,
- dizziness.

Common side effects (more than 1 person in every 100 treated but fewer than 1 person in every 10 treated)

- 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 atrio-ventricular 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 [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nebinad

Do not store above 30°C.

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

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 Nebinad contains

- The active substance is nebivolol. Each tablet contains 5 mg of nebivolol equivalent to 5.45 mg of nebivolol hydrochloride.
- The other ingredients are:
Lactose Monohydrate,
Crospovidone Type A,
Poloxamer 188,
Povidone K 30,
Microcrystalline Cellulose,
Magnesium Stearate.

What Nebinad looks like and contents of the pack

Nebinad tablets are white, round, biconvex tablets, cross-scored on one side, with a diameter of 9 mm approximately.

Nebinad can be divided into equal quarters.

The tablets are provided in PVC/PE/PVDC/Aluminium foil blisters, packed in carton packs.
Packs of 7, 10, 14, 20, 28, 30, 50, 56, 60, 90, 100, 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Recordati Polska sp. z o.o.
ul. Królewska 16
00-103 Warszawa

Manufacturer

Specifar S.A.
1, 28 Octovriou str., Ag. Varvara
123 51 Athens
Greece

This leaflet was last revised in 02/2019