Package leaflet: Information for the patient

Nebicor 2,5 mg; 5 mg tablets
Nebivolol

adipharm

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 Nebicor is and what it is used for
Nebicor belongs to the group of the so-called beta blockers and is used for treatment of high blood pressure (hypertension). Nebicor may also be used for treatment of stable mild to moderate chronic heart failure, in addition to the main treatment in patients aged 70 years or more. The heart failure is a heart disorder that most frequently leads to easy fatigue, breathlessness, ankle edema etc.

2. What you need to know before you take Nebicor
Do not take Nebicor
- if you are allergic (hypersensitive) to the active substance or to any of the other ingredients of the product.
- if you have any of the following disorders:
- low blood pressure, disturbed circulation of the hands and the legs, low heart rate (under 60 beats per minute) or some other heart disorders;
- your heart failure is newly appeared or is recently worsened or if you were given intravenously some medicines for improvement of the work of the heart;
- asthma or breathing difficulty (presently or in the past);
- some adrenal gland tumours;
- impaired liver function;
- metabolic disorder (metabolic acidosis), e.g. diabetic ketoacidosis.
- if you use floctafenine or sultopride containing medicines.

Warnings and precautions
Take special care when using Nebicor, if
- You have wheezes or other similar respiratory problems as well as allergy to insect bites, to foods or other substances. In this case, you should not use this medicinal product before discussing it with your doctor. Nebicor may increase your sensitivity to allergens.
- You suffer or have suffered before from psoriasis (type of skin rash). Nebicor may worsen your psoriasis.
- You suffer from diabetes. Nebicor has no impact on the blood sugar level but it may mask some of the symptoms of low blood sugar (e.g. the shaking and the increased heart rate).
- You suffer from increased function of the thyroid gland. In this case, Nebicor may mask the symptoms of increased heart rate.

If something of the listed above is valid for you, please consult your doctor before starting treatment with this medicinal product.
If you have problems with your kidneys, Nebicor may not be appropriate for treatment of your heart failure and you should discuss this problem with your doctor.
If during treatment with this product you notice that your heart rate is slowed down (your heart starts to beat slower), inform your doctor as soon as possible. He/she may prescribe you a lower dose or advise you to gradually discontinue your treatment with this medicine.
If you are to undergo an eligible surgery under general anaesthesia or dental treatment, please inform your doctor or dentist about your treatment with Nebicor.
Your treatment with Nebicor should not be abruptly discontinued.
Please check with your doctor if you are not sure or have any further questions on your treatment with this medicinal product or your disease.

Children and adolescents
No studies in children and adolescents were performed. Therefore, the use of the product in this group of patients is not recommended.

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

This medicinal product may influence the effect of other medicines and other medicinal products may influence Nebicor action.
Always inform your doctor or pharmacist if you take any of the following medicines concomitantly with Nebicor:
- some medicines used for treatment of the heart and the blood vessels such as calcium channel blockers (e.g. verapamil, diltiazem, nifedipine etc.), anti-arrhythmic agents (such as quinidine and amiodarone) and sympathomimetics. Verapamil should not be administered intravenously during treatment with Nebicor.
- antipsychotics (medicines for treatment of anxiety, e.g. barbiturates, phenothiazines) and tricyclic antidepressants.
- anaesthetics – always inform the anesthesiologist that you are taking Nebicor.
- medicines for decreasing gastric acidity (e.g. cimetidine) – you should take Nebicor during meals and the antacid agent – between meals
- antihistamines (for treatment of various allergic conditions)
- other beta blockers, e.g. those administered in the form of eye drops
- clonidine. If you are taking clonidine and Nebicor concomitantly, you should not stop taking clonidine until your doctor tells you. If clonidine or Nebicor administration should be discontinued, your doctor will give you detailed instructions how to do this.

Nebicor with food, drink and alcohol
There is no evidence that a special diet or limitaions of some types of foods and drinks is needed during treatment with Nebicor tablets.

Pregnancy, breast-feeding and fertility
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.

Nebicor should not be used during pregnancy and breast-feeding unless your doctor considers it absolutely necessary.

Driving and using machines
There are no studies on the ability for driving and using machines. This medicine may cause dizziness or fainting due to reduction of blood pressure.

Nebicor contains lactose
This medicinal product contains lactose. If you know that you suffer from intolerance to some sugars, please inform your doctor before taking this medicine.

3. How to take Nebicor
The dosage and duration of treatment are determined by your doctor depending on your condition.
Always take Nebicor exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Treatment of high blood pressure (hypertension)
The usual dose is 5 mg (one 5 mg tablet or two 2,5 mg) daily, preferably at one and the same time of the day. The tablets may be taken during meals.
The antihypertensive (blood pressure lowering) effect is manifested within 1-2 weeks from the beginning of treatment. In some cases, 4 weeks are necessary for attaining optimal effect.
Patients with renal failure: In patients with renal failure the recommended initial dose is 2,5 mg (half a 5 mg tablet or one

2,5 mg) daily. If necessary, the daily dose may be increased to 5 mg.
Patients with liver failure: There are limited data in patients with liver failure or impaired liver function. Therefore, the use of the medicinal product in these patients is contraindicated.
Elderly patients: The recommended initial dose in patients over 65 years of age is 2,5 mg daily. If necessary, the daily dose may be increased to 5 mg. Nevertheless, due to the limited experience in patients over 75 years of age, this medicinal product should be used cautiously and under strict medical control.
Children and adolescents: No studies in children and adolescents were performed. Therefore, the use of the product in this group of patients is not recommended.

Chronic heart failure
Treatment in chronic heart failure should begin with gradual dose increase until the optimal maintenance dose for each patient is attained.
Dose titration (increase) should be done at 1-2-week interval depending on the individual tolerability of the patient as follows: the initial dose of 1,25 mg nebivolol should be increased to 2,5 mg nebivolol once daily, then to 5 mg once daily and finally to 10 mg once daily. The maximum recommended dose is 10 mg once daily.
Usually, treatment of stable heart failure with nebivolol is continuous.
If discontinuation of treatment is needed the dose should be gradually reduced (reduction by half, every week).
Children and adolescents: No studies in children and adolescents were performed. Therefore, the use of the product in this group of patients is not recommended.
Check with your doctor if you are not sure or have any further questions on your treatment with this medicinal product.

If you take more Nebicor than you should
If you have taken a higher than the prescribed dose, immediately seek medical attention (go to the nearest hospital or to an emergency centre). This is also valid in the cases when you are feeling well and have no signs of overdose. Take the pack of the medicine with you.

If you forget to take Nebicor
Take the missed dose straight away when you remember and then continue with your usual treatment schedule. If it is almost time for the next dose, omit the forgotten dose. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Nebicor
Your treatment with Nebicor should not be discontinued abruptly. Your doctor will determine the duration of treatment and the method of its discontinuation.
If you have any further questions on the use of this medicine, please ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, Nebicor can cause side effects, although not everybody gets them.
During the administration of the product for treatment of high blood pressure the following adverse reactions were observed:
- Common (reported in less than 1 in 10 but in more than 1 in 100 patients):
- headache;
- dizziness;
- tingling;
- breathing difficulty;
- constipation;
- nausea;
- diarrhea;
- fatigue;
- edema of the hands and the legs.

Uncommon (in less than 1 in 100 patients but in more than 1 in 1 000 patients):
- nightmares;
- depression;
- impaired vision;
- slowed heart rate or other heart disorders (slowed impulse conduction) of the heart;
- low blood pressure;
- bronchospasm (spasm of the bronchi);
- impaired digestion;
- increased formation and accumulation of gases in the abdomen;
- vomiting;
- skin rash and itching;
- impotence.

Very rare (in less than 1 in 10 000 patients):
- severe blood pressure reduction (fainting);
- worsening of psoriasis.

During the administration of the product for treatment of chronic heart failure the following side effects were observed:
- slowed heart rate;
- dizziness;
- worsening of the heart failure;
- low blood pressure (dizziness upon abrupt standing);
- intolerability to the medicine;
- irregular heart rhythm;
- edema (mainly in the lower extremities).

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.
By reporting side affects you can contribute to providing more information on the safety of this medicine.

5. How to store Nebicor
Store at temperature below 30 °C.
Keep this medicine out of the sight and reach of children.

Do not use the medicinal product after the expiry date which is stated on the package. The expiry date refers to the last day of that month.
Do not use Nebicor if you notice that the integrity of the package is spoilt and/or the appearance of the tablets is different from that described at the end of this leaflet.
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 Nebicor contains

Nebicor 2,5 mg tablets
- The active substance is nebivolol 2,5 mg (as nebivolol hydrochloride 2,725 mg).
- The other ingredients (excipients) are: Lactose Monohydrate, Crospovidone Type A, Poloxamer 188, Povidone, Microcrystalline Cellulose, Magnesium Stearate.

Nebicor 5 mg tablets
- The active substance is nebivolol 5 mg (as nebivolol hydrochloride 5,45 mg).
- The other ingredients (excipients) are: Lactose Monohydrate, Crospovidone Type A, Poloxamer 188, Povidone, Microcrystalline Cellulose, Magnesium Stearate.

What Nebicor looks like and contents of the pack

Nebicor 2,5 mg
The tablets are white without scores.
15 tablets in blister.
2 (two) blisters with a leaflet in carton box

Nebicor 5 mg
The tablets are white, round, biconvex with two (crossed) scores on one side.
The scores make dividing of the tablet in four equal parts possible.
15 tablets in blister
2 (two) blisters with a leaflet in carton box

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