Package leaflet: Information for the user

# Nebicor H 5 mg /12,5 mg film-coated tablets

***Nebivolol / Hydrochlorothiazide***

adipharm

**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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What Nebicor H is and what it is used for

Nebicor H contains nebivolol and hydrochlorothiazide as the active ingredients.
- Nebivolol is 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 and controls heart pumping strength. It also widens blood vessels, which helps to lower your blood pressure.
- Hydrochlorothiazide is a diuretic, that acts by increasing the amount of urine you produce.

Nebicor H is a one-tablet combination of nebivolol and hydrochlorothiazide and is used for the treatment of raised blood pressure (hypertension). It is used instead of the two separate products for those patients who are already taking them together.

## 2. What you need to know before you take Nebicor H

**Do not takeNebicor H**
- if you are allergic to nebivolol or to hydrochlorothiazide or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other sulphonamide-derived substances (like hydrochlorothiazide, which is a sulphonamide-derived drug)
- if you have one or more of the following disorders:
- very slow heartbeat (less than 60 beats per minute)
- certain other serious heart rhythm problems (e.g. sick sinus syndrome, sino-atrial block, 2 nd and 3rd degree atrioventricular block).
- 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
- low blood pressure
- serious circulation problems in the arms or legs
- untreated phaeochromocytoma, a tumour located on top of the kidneys (in the adrenal glands) - severe kidney problems, complete absence of urine (anuria)
- a metabolic disorder (metabolic acidosis), e.g., diabetic ketoacidosis.
- asthma or wheezing (now or in the past)
- liver function disorder
- high blood calcium, low blood potassium, low blood sodium levels that are persistent and resistant to treatment
- high uric acid levels with gout symptoms

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Nebicor H

Inform your doctor if you have or develop one of the following problems:
- a type of chest pain due to spontaneously occurring heart cramp, called Prinzmetal angina
- 1 st degree heart block (a kind of mild heart conduction impairment that affects heart rhythm)
- abnormally slow heartbeat
- untreated chronic heart failure
- lupus erythematosus (a disorder of the immune system, i.e. your body's defence system)
- psoriasis (a skin disease characterised by scaly pink patches) or if you have ever had psoriasis
- overactive thyroid gland: this medicine may mask the signs of an abnormally fast heart rate due to this condition
- poor circulation in the arms or legs, e.g. Raynaud's disease or syndrome, cramp-like pains when walking
- allergy: this medicine may intensify your reaction to pollen or other substances you are allergic to
- prolonged breathing problems
- diabetes: this medicine could conceal the warning signs of a low sugar level (e.g. palpitations, fast heartbeat); your doctor will also tell you to check your blood sugar more often while taking Nebicor H, as the dose of your antidiabetic drugs may need to be adjusted
- kidney problems: your doctor will check your kidney function to make sure it does not get worse. If you have serious kidney problems do not take Nebicor H (see section 'Do not take Nebicor H')
- if you tend to have low blood potassium, and especially if you suffer from prolonged QT syndrome (a kind of ECG abnormality) or you are taking digitalis (to help your heart pump); you are more likely to have low blood potassium if you suffer from liver cirrhosis, or have had too rapid a loss of water due to a strong diuretic treatment, of if your intake of potassium with food and drinks is inadequate
- if you have to have surgery, always inform your anaesthetist that you are on Nebicor H before being anaesthetised.
- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Nebicor H.

During treatment
- Nebicor H may increase blood fat levels and uric acid.
- Nebicor H may affect the levels of certain salts in your blood (such as magnesium, potassium, sodium and chloride):: your doctor may carry out blood tests to check the level of salts in your blood from time to time. This may cause symptoms such as dry mouth, thirst, weakness, tiredness, muscle weakness, pain or cramps, a racing heart, dizziness, low blood pressure, restlessness, feeling or being sick and passing less urine. Tell your doctor if you notice any of these symptoms
- The hydrochlorothiazide in Nebicor H may cause your skin to be oversensitive to sunlight or artificial UV light. Stop taking Nebicor H and tell your doctor if you get a rash, itchy spots or sensitive skin during treatment (see also Section 4).
- Tell your doctor if you notice changes in your vision or pain in the eyes. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Nebicor H. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

Laboratory tests
- Anti-dope test: Nebicor H could cause a positive anti-dope test.
- Nebicor H may alter the test results for parathyroid function. Tell your doctor or hospital that you are talking Nebicor H before undergoing these tests.

**Children and adolescents**

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

Other medicines and Nebicor H

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

Always tell your doctor if you are using or receiving any of the following medicines in addition toNebicor H:
- Medicines that, as well as Nebicor H, may influence the blood pressure and/or heart function:
- Medicines for controlling blood pressure or medicines for heart problems (such as amiodarone, amlodipine, cibenzoline, clonidine, digoxin, diltiazem, disopyramide, dofetilide, felodipine, flecainide, guanfacine, hydroquinidine, ibutilide, lacidipine, lidocaine, mexiletine, methyldopa, moxonidine, nicardipine, nifedipine, nimodipine, nitrendipine, propafenone, quinidine, rilmenidine, sotalol, verapamil)
- Sedatives and therapies for psychosis (a mental illness) e.g. amisulpiride, barbiturates (also used for epilepsy), chlorpromazine, cyamemazine, droperidol, haloperidol, levomepromazine, narcotic drugs, phenothiazine (also used for vomiting and nausea), pimozide, sulpiride, sultopride, thioridazine, tiapride trifluoperazine
- Medicines for depression e.g. amitriptyline, fluoxetine, paroxetine
- 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
- Baclofen (an antispasmodic drug)
- Amifostine (a protective medicine used during cancer treatment)
- Cholestyramine or colestipol (medicines used to lower cholesterol)
- Medicines whose effect or toxicity may be increased by Nebicor H:
- Lithium, used as a mood stabiliser
- Cisapride (used for digestive problems)
- Bepridil (used for angina)
- Diphemanil (used for excessive sweating)
- Medicines used for infections: erythromycin given by infusion or injection, pentamidine and sparfloxacin, amphotericin and penicillin G sodium, halofantrine (used for malaria)
- Vincamine (used for brain circulation problems)
- Mizolastine and terfenadine (used for allergy
- Diuretics and laxatives
- Medicines used to treat acute inflammation: steroids (e.g. cortisone and prednisone), ACTH (adrenocorticotropic hormone) and medicines derived from salicylic acid (e.g. acetylsalicylic acid/aspirin and other salicylates)
- Carbenoxolone (used for heartburn and stomach ulcer)
- Calcium salts, used as supplements for bone health
- Medicines used to relax muscles (e.g. tubocurarine)
- Diaxozide, used to treat low blood sugar and high blood pressure
- Amantadine, an antiviral medicine
- Cyclosporine, used to suppress the body's immune response - Iodinated contrast media, used for contrast in X-ray scans
- Anti-cancer medicines (e.g. cyclophosphamide, fluorouracil, methotrexate)
- Medicines whose effect may be decreased by Nebicor H:
- Blood sugar-lowering medicines (insulin and oral antidiabetic drugs, metformin)
- Medicines for gout (e.g. allopurinol, probenecid and sulfinpyrazone)
- Medicines like noradrenalin, used to treat low blood pressure or slow heart rate
- Medicines for pain and inflammation (non-steroidal anti-inflammatory drugs), as they may reduce the blood pressure lowering effect of Nebicor H
- Medicines for treating excessive stomach acid or ulcers (antacid), e.g. cimetidine: you should take Nebicor H during a meal and the antacid between meals.

**Nebicor H with alcohol**

Take care when drinking alcohol while you are taking Nebicor H, as you

may feel faint or dizzy. If this happens to you, do not drink any alcohol, including wine, beer or alcopops.

**Pregnancy and breast-feeding**
You must tell your doctor if you are pregnant or if you think that you are. Usually, your doctor will advise you to take another medicine instead of Nebicor H, as Nebicor H is not recommended during pregnancy. This is because the active ingredient hydrochlorothiazide crosses the placenta. The use of Nebicor H during pregnancy may cause potentially harmful foetal and neonatal effects.
Tell your doctor if you are breast-feeding or about to start breast-feeding. Nebicor H is not recommended for mothers who are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**
This medicine may cause dizziness or fatigue. If affected, **do not** drive or operate machinery.
Nebicor H 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.

## 3. How to take Nebicor H
Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.
The recommended dose is 1 tablet a day with some water, preferably at the same time of day.
Nebicor H may be taken before, during or after a meal, but you can take it independently of meals.

**Use in children and adolescents**
Do not give Nebicor H to children or adolescents.
**If you take more Nebicor H 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 overdose are very slow heart beat (bradycardia), low blood pressure with possible fainting, breathlessness such as in asthma, acute heart failure, excessive urination with consequent dehydration, nausea and somnolence, muscle spasms, heart rhythm disturbances (especially if you are also taking digitalis or medicines for heart rhythm problems).

**If you forget to take Nebicor H**
If you forget a dose of Nebicor H, 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 to make up for a forgotten dose. Repeated skipping, however, should be avoided.

**If you stop taking Nebicor H**
Always consult your doctor before stopping Nebicor H treatment.
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.

**Stop taking Nebicor H and seek medical help immediately** if you have any of the following reactions:
- 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). *Frequency not known (cannot be estimated from the available data)*

The following side effects have been reported with nebivolol:

**Common** (may affect up to 1 in 10 people):
- headache
- dizziness
- tiredness
- an unusual burning, pricking, tickling, or tingling sensation
- diarrhoea
- constipation
- nausea
- shortness of breath
- swollen hands or feet

**Uncommon** (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, 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** (may affect up to 1 in 10,000 people)
- fainting
- worsening of psoriasis (a skin disease characterised by scaly pink patches)

**Not known** (cannot be esitimated from the available data)
The following side effects have been reported only in some isolated cases:
- kind of skin rash notable for pale red, raised, itchy bumps of allergic or non allergic causes (urticaria)
- seeing or hearing things that are not real (hallucinations)
- loss of contact with reality (psychosis)
- blood circulation problems in the fingers, toes, arms and legs which may result in pallor, blueing or tingling of the fingers and toes (Raynaud's syndrome)
- dry eyes, scarring or thickening of the eylids or white of the eye

The following side effects have been reported with hydrochlorothiazide:

**Allergic reactions**
- whole-body allergic reaction (anaphylactic reaction)

**Heart and circulation**
- heart rhythm disturbances, palpitations
- changes in the electrocardiogram
- sudden fainting when standing upright, formation of blood clots in veins (thrombosis) and embolism, circulatory collapse (shock)

**Blood**
- changes in the number of blood cells, such as: decreased white blood cells, decreased blood platelets, decreased red blood cells; impaired production of new blood cells by the bone marrow
- altered levels of body fluids (dehydration) and blood chemicals, in particular decreased potassium, decreased sodium, decreased magnesium, decreased chlorine and increased calcium
- increased uric acid levels, gout, increased blood glucose, diabetes, metabolic alkalosis (a disorder of metabolism), increased blood cholesterol and/or triglycerides

**Stomach and gut**
- lack of appetite, dry mouth, nausea, vomiting, stomach discomfort, abdominal pain, diarrhoea, fewer bowel movements (constipation), absence of bowel movements (ileus paralytic), flatulence
- inflammation of the glands that produce saliva, inflammation of the pancreas, increased blood amylase level (a pancreatic enzyme)
- yellowing of the skin (jaundice), inflammation of the gall bladder

**Chest**
- respiratory distress, lung inflammation (pneumonitis), formation of fibrous tissue in the lungs (interstitial lung disease), fluid accumulation in the lung (pulmonary oedema)

**Nervous system**
- vertigo (spinning sensation)
- convulsions, depressed level of consciousness, coma, headache, dizziness
- apathy, confusional state, depression, nervousness, restlessness, sleep disturbances
- unusual burning, pricking, tickling, or tingling skin sensations
- muscle weakness (paresis)

**Skin and hair**
- itchiness, purple spots/blotches on the skin (purpura), hives (urticaria), increased sensitivity of your skin to sunlight, rash (including erythema multiforme), facial rash and/or patchy redness that can cause scarring (cutaneous lupus erythematosus), inflammation of blood vessels with consequent death of tissue (vasculitis necrotising), peeling, redness, loosening, and blistering of the skin (toxic epidermal necrolysis)

**Eyes and ears**
- yellow vision, blurred vision, worsening of myopia, decreased tear production, decrease in vision and eye pain (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute myopia or acute angle-closure glaucoma)

**Joint and muscles**
- muscle spasm, muscle pain

**Urinary**
- kidney dysfunction, acute kidney failure (reduced urine production and build-up of fluid and wastes in your body), inflammation of the connective tissue within the kidneys (interstitial nephritis), sugar in the urine

**Sexual**
- Erection disturbances

**General/Other**
- General weakness, tiredness, fever, thirst

**Not known** (cannot be esitimated from the available data)
- Skin and lip cancer (Non-melanoma skin cancer)

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Nebicor H
Keep this medicine out of the sight and reach of children.
This medicinal product does not require any special storage condition.
Do not store above 30°C. Store in the original package in order to protect from moisture.
Do not use this medicine after the expiry date which is stated on the box and on the blister pack after 'EXP'. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater . 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 H contains**
- The active substances are nebivolol 5 mg (as nebivolol hydrochloride) and 12,5 mg of hydrochlorothiazide
- The other ingredients are:

tablet core: lactose monohydrate, polysorbate 80 (E433), hypromellose (E15), maize starch, microcrystalline cellulose (PH 102), crosscarmellose sodium, colloidal anhydrous silica (E551), magnesium stearate (E572)
film coat: hypromelose, hyprolose, triglicerides, titanium dioxide (E171), polyethylene glycol, iron oxide (E172).

**What Nebicor H looks like and contents of the pack**
Nebicor H is a pink round film-coated tablet.
Each box contains 3 blisters (PVC/PVDC/Alu) of 10 film- coated tablets each.

**Manufacturer:**
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