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PACKAGE LEAFLET: Information for the user
Nebivolol STADA® 5 mg tablets
Active substance: Nebivolol

Read the entire package leaflet carefully before you start taking this medicine because it contains important information.
Keep the package leaflet. You may want to read it again later.
If you have any further questions, please ask your doctor or pharmacist.
This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this package leaflet. See section 4.

What this package leaflet contains:

1. What is Nebivolol STADA® and what is it used for?

Nebivolol STADA® contains nebivolol, a cardiovascular drug from the group of selective beta-receptor blockers (i.e., it acts specifically on the cardiovascular system). It prevents a rapid heartbeat and regulates the heart's contraction force. Additionally, it dilates blood vessels, which also helps to lower blood pressure.

Nebivolol STADA® is used
for the treatment of non-organic high blood pressure (essential hypertension)
for the treatment of stable mild to moderate chronic heart failure in patients aged 70 years and older in addition to standard treatment.

2. What should you consider before taking Nebivolol STADA® note?

Nebivolol STADA® must NOT be taken
if you are allergic to nebivolol or any of the other ingredients of this medicine listed in section 6
if you suffer from one or more of the following conditions
- low blood pressure
- severe circulatory disorders in the arms or legs
- very slow heartbeat (less than 60 beats per minute) or irregular heartbeat (sick sinus syndrome)
- certain other severe heart rhythm disorders (e.g., second and third degree AV block, sinoatrial block)

- newly occurring or acutely worsening heart failure, if you are in shock due to a worsening of heart failure (cardiogenic shock) or if you are undergoing treatment for circulatory shock due to acute heart failure directly via a venous access (intravenously)
- existing or past bronchial asthma or wheezing due to bronchial constriction or any other existing or previously experienced condition that impairs breathing
- untreated pheochromocytoma; a tumor located on the kidneys (in the so-called adrenal glands)
- liver dysfunction
- a certain metabolic disorder (metabolic acidosis) e.g., diabetic ketoacidosis.

Warnings and precautions
Please talk to your doctor or pharmacist before taking Nebivolol AL

unusually slow heartbeat
chest pain caused by sudden spasms of the coronary arteries, known as Prinzmetal's angina
untreated chronic heart failure and ischemic heart disease (circulatory disorders of the heart)
AV block of the 1st degree (a mild conduction disorder of the heart that affects the heart rhythm)
poor circulation in the arms or legs, e.g. e.g. Raynaud's disease or syndrome, cramp-like pain when walking
Diabetes mellitus: This medicine does not affect blood sugar levels, but it could mask the warning signs of low blood sugar (palpitations, rapid heartbeat).
Hyperthyroidism: This medicine can mask the signs of an unusually rapid heartbeat due to this condition.
Allergies: This medicine can enhance your reaction to pollen or other substances to which you are allergic.
persistent breathing problems associated with coughing (if you know you suffer from chronic obstructive pulmonary disease [COPD])
Psoriasis (a skin condition that is associated with scalypink patches), or if you have ever had psoriasis
if you need to undergo surgery. Always inform your anesthetist before anesthesia that you are taking Nebivolol STADA® .

If you suffer from severe kidney dysfunction, you should not take Nebivolol STADA® . Please discuss your kidney dysfunction with your doctor beforehand.

At the start of your treatment for chronic heart failure, your doctor will regularly examine you (see section 3: How to take Nebivolol STADA®). This treatment should not be stopped suddenly unless your doctor deems it absolutely necessary (see section 3: How to take Nebivolol STADA® to take?).

Children and adolescents
Due to lack of data on use in children and adolescents under 18 years, Nebivolol STADA® is not recommended for this age group.

Effects of misuse for doping purposes
The use of Nebivolol STADA® can lead to positive results in doping tests. The health consequences of using Nebivolol STADA® as a doping agent cannot be foreseen, and serious health risks cannot be ruled out.

Use of Nebivolol STADA® together with other medicines
Inform your doctor or pharmacist if you are using, have recently used, or intend to use other medicines.

Certain medicines must not be used simultaneously with Nebivolol STADA® . Other medicines require specific adjustments (e.g., dosage) when used simultaneously.

Please especially inform your doctor if you are taking any of the following medicines in addition to Nebivolol STADA® apply

- Medicines for the treatment of high blood pressure or heart diseases (such asAmiodarone, Amlodipine, Cibenzoline, Clonidine, Digoxin, Diltiazem,
  Disopyramide, Felodipine, Flecainide, Guanfacine, Hydroquinidine, Lacidipine, Lidocaine, Methyldopa, Mexiletine, Moxonidine, Nicardipine, Nifedipine, Nimodipine,
  Nitrendipine, Propafenone, Quinidine, Rilmenidine, Verapamil)
- Sedatives and medicines for the treatment of psychoses (a psychiatric disorder), such as barbiturates (also used in epilepsy), phenothiazines (also used against nausea and vomiting) e.g. Thioridazine
- Medicines for the treatment of depressive disorders, such as tricyclic antidepressants, Paroxetine, Fluoxetine
- Baclofen (a muscle relaxant medicine)
- Amifostine (a medicine used in cancer treatment)
- Medicines used for anesthesia during an operation
- Medicines for bronchial asthma, a blocked nose, or certain eye diseases like glaucoma (increased intraocular pressure) or for pupil dilation.

All these medicines, like Nebivolol, can affect blood pressure and/or heart function.

- Medicines for the treatment of excessive stomach acid production or stomach ulcers (antacids), such as Cimetidine. You should take Nebivolol STADA® with a meal and the antacid between meals.
- Insulin or tablets for the treatment of diabetes mellitus. Although Nebivolol does not affect blood sugar, certain warning signs of low blood sugar (e.g., rapid heartbeat) may be masked by concurrent use.

Taking Nebivolol STADA® together with food and drinks
Nebivolol STADA® can be taken with a meal or on an empty stomach. However, the tablet should be taken with some water.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, or if you suspect you are pregnant or intend to become pregnant, ask your doctor or pharmacist for advice before using this medicine.

The use of Nebivolol STADA® during breastfeeding is not recommended.

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

Driving and using machines
This medicine can cause dizziness and fatigue. If you are affected, you must not drive a vehicle or operate tools and machines.

Nebivolol STADA® contains lactose
Please only take Nebivolol STADA® after consulting your doctor if you know that you have an intolerance to certain sugars.

3. How to take Nebivolol STADA® to take?

Always take this medicine exactly as agreed with your doctor or pharmacist. Please check with your doctor or pharmacist if you are not sure.

Nebivolol STADA® can be taken before, during, or after meals, but it can also be taken independently of meals. The tablet should be taken with some water (e.g., 1 glass of water).

Treatment of high blood pressure (hypertension)

The usual dose is: 1 tablet once daily. This dose should be taken at the same time each day if possible.
Older patients over 65 years and patients with impaired kidney function usually start with ½ (half) a tablet per day. If necessary, the daily dose can be increased to 1 tablet.
A blood pressure-lowering effect is seen after 1 to 2 weeks of treatment. Occasionally, the optimal effect is achieved only after 4 weeks.

Treatment of chronic heart failure

An experienced doctor will start your treatment and monitor it closely.
Your doctor will start the treatment with ¼ (a quarter) tablet daily. After 1 to 2 weeks, the dosage can be increased to ½ (half) a tablet per day, then possibly to 1 tablet per day, and finally possibly to 2 tablets per day until the dose suitable for you is reached. Your doctor will prescribe the most suitable dose for you at each step, and you should follow his instructions carefully.
The recommended maximum dose is 2 tablets (10 mg Nebivolol) per day.
At the start of treatment and after each dose increase, it is necessary for you to be carefully monitored by an experienced doctor for at least 2 hours.
If necessary, your doctor can also reduce the dose.
You should not stop the treatment abruptly, as this may worsen your heart failure.
Take your medicine once daily, preferably at the same time each day.

Patients with severe renal impairment should not take this medication, as there is no experience with the treatment of these patients with Nebivolol.

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If your doctor has prescribed you ¼ (a quarter) or ½ (a half) tablet per day, you must break the tablet along the 'score lines' before taking it. Nebivolol STADA® tablets have a cross-shaped score line to facilitate individual dosing. Please follow the instructions below for splitting Nebivolol STADA® tablets.
Place the tablet with the score line facing up on a smooth, firm surface.
Apply pressure to the tablet from above with your thumb, it will then break into four equal parts.

Your doctor may combine Nebivolol STADA® with other medications to treat your condition.

Nebivolol STADA® should not be used in children and adolescents under 18 years of age.

If you have taken more Nebivolol STADA® than you should
Inform your doctor or pharmacist immediately if you have accidentally taken too high a dose of this medicine.

The most common symptoms and signs of an overdose of Nebivolol STADA® are very slow heartbeat (bradycardia), low blood pressure (hypotension), which can lead to fainting, shortness of breath as in bronchial asthma (bronchospasm), and sudden (acute) heart failure.

If you forget to take Nebivolol STADA® If you forget to take a dose of Nebivolol STADA
If you miss a dose of Nebivolol STADA and remember shortly afterwards, take the dose intended for that day as usual. However, if there is already a significant delay (e.g., several hours), so that the next dose is almost due, skip the missed dose and take the next scheduled dose at the usual time. Do not take a double dose. Repeated omissions should be avoided. if you forget but notice it shortly after, then take the dose intended for that day as usual. However, if there is already a significant delay (e.g., several hours), so that the next dose is due soon, skip the missed dose and take the next scheduled dose at the usual time. Do not take a double dose. Repeated omissions should be avoided.

If you are taking Nebivolol STADA Talk to your doctor before stopping treatment with Nebivolol STADA ®
, regardless of whether you are taking the medicine for high blood pressure or chronic heart failure. You should not stop treatment with Nebivolol STADA discontinue, regardless of whether you are taking the medication for high blood pressure or chronic heart failure.

suddenly, as this may temporarily worsen your heart failure. If it is necessary to stop treatment for chronic heart failure with Nebivolol STADA® do not stop suddenly, as this may temporarily worsen your heart failure. If it is necessary to discontinue the treatment of chronic heart failure with Nebivolol STADA® to discontinue, the daily dose should be gradually reduced by halving the dose at weekly intervals.

If you have further questions on the use of the medicine, ask your doctor or pharmacist.

4. What side effects are possible?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

When Nebivolol STADA® is used to treat high blood pressure, the following side effects are possible

Common side effects (in less than 1 in 10, but more than 1 in 100 treated patients):
- Headache
- Dizziness
- Fatigue
- Sensory disturbances such as itching or tingling (paresthesia)
- Diarrhea
- Constipation
- Nausea
- Shortness of breath
- Accumulation of fluid in the tissues, which can lead to swelling, especially of the legs and ankles (edema).

Occasional side effects (in less than 1 in 100, but more than 1 in 1000 treated patients):
- Slow heartbeat or other heart problems
- Low blood pressure
- Cramp-like pain in the legs when walking (intermittent claudication)
- Visual disturbances
- Impotence
- Depression
- Digestive disorders (dyspepsia), flatulence, vomiting
- Rash, itching
- Shortness of breath as in bronchial asthma due to sudden spasms of the respiratory muscles (bronchospasm)
- Nightmares.

Very rare side effects (in less than 1 in 10,000 treated):
- Sudden fainting spells
- Worsening of psoriasis (a skin condition characterized by scaly pink patches).

Frequency not known (frequency cannot be estimated from the available data):
- Swelling of lips, eyes, or tongue (angioneurotic edema), possibly associated with sudden shortness of breath
- Allergic (hypersensitivity) reactions.

The following additional side effects have been observed with drugs similar to nebivolol Hallucinations, psychiatric disorders and confusion, cold fingers and toes that sometimes turn pale or blue, dry eyes, and a severe disease of the eyes and mouth.

In a clinical study on heart failure, the following side effects were reported

Very common side effects (in more than 1 in 10 treated):
- Slow heartbeat
- Dizziness.

Common side effects (in less than 1 in 10, but more than 1 in 100 treated):
- Worsening of heart failure
- Low blood pressure (e.g., feeling faint after standing up quickly)

Intolerance reactions
A mild conduction disorder affecting the heart rhythm (first-degree AV block)
Swelling of the lower limbs (e.g., swollen ankles).

Reporting side effects
If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report sideeffects directly:
Federal Institute for Drugs and Medical Devices
Dept. of Pharmacovigilance
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn
Website: www.bfarm.de

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How is Nebivolol STADA® to store?

Keep this medicine out of the reach of children.

Do not use this medicine after the expiry date stated on the carton and blister pack. The expiry date refers to the last day of that month.

Do not store above +30 °C.

Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. This helps protect the environment.

6. Contents of the pack and other information

What Nebivolol STADA® contains
The active substance is nebivolol.

1 tablet contains 5 mg nebivolol as nebivolol hydrochloride.

The other ingredients are
Croscarmellose sodium, crospovidone (type A), lactose monohydrate, magnesium stearate (Ph.Eur.), pregelatinized maize starch, povidone K30, colloidal anhydrous silica.

What Nebivolol STADA® looks like and contents of the pack

Nebivolol STADA® is only available in the strength of 5 mg. White, round, biconvex tablet with a cross break line on both sides.

Nebivolol STADA® is available in packs of 30, 50, and 100 tablets.

Pharmaceutical company
STADApharm GmbH, Stadastraße 2–18, 61118 Bad Vilbel

Phone: 06101 603-0, Fax: 06101 603-259, Internet: www.stada.de

Manufacturer
STADA Arzneimittel AG, Stadastraße 2–18, 61118 Bad Vilbel

This medicinal product is authorized in the member states of the European Economic Area (EEA) under the following names:approved invoices:
Belgium: Nebivolol EG 5 mg comprimés
Estonia: Nemirostad 5 mg tabletid
France: Nebivolol EG 5 mg, comprimé
Ireland: Nebimel 5 mg tablets
Italy: Nebivololo EG 5 mg tablets
Latvia: Nemirostad 5 mg tablets
Lithuania: Nemirostad 5 mg tablets
Luxembourg: Nebivolol EG 5 mg tablets
Netherlands: Nebivolol CF 5 mg, tablets
Austria: Nebivolol STADA® 5 mg tablets
Portugal: Nebivolol Ciclum 5 mg tablets

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