

Nebivolol STELLA Tablet 5mg

Nebivolol (as nebivolol hydrochloride) 5 mg

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What Nebivolol STELLA Tablet 5mg is used for

- It is used to treat raised blood pressure (hypertension).
- Nebivolol is also used to treat mild and moderate chronic heart failure in patients aged 70 years or over, in addition to other therapies.

How Nebivolol STELLA Tablet 5mg works

Nebivolol STELLA Tablet 5mg tablets 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 the blood pressure.

Before you use Nebivolol STELLA Tablet 5mg

- When you must not use it

- If you are allergic to nebivolol or any of the other ingredients of this medicine.
- If you have one or more of the following disorders:
 - low blood pressure
 - serious circulation problems in the arms or legs
 - very slow heartbeat (less than 60 heart beats per minute)
 - certain other serious heart rhythm problems (e.g. 2nd and 3rd degree atrioventricular block, heart conduction disorders)
 - 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
 - asthma or wheezing (now or in the past)
 - 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

If you think any of these apply to you, or if you are in any doubt at all, consult your doctor before taking this drug.

- Before you start to use it

If any of the situations mentioned below apply to you, you should tell your doctor before taking this drug:

Inform your doctor if you have or develop any 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.
- 1st degree heart block (a kind of light heart conduction disorder that affects the 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 conceal the warning 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.
- if you have to have surgery, always inform your anaesthetist that you are on Nebivolol before being anaesthetised.
- If you have a serious kidney problems do not take Nebivolol 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).
- This treatment should not be stopped abruptly unless clearly indicated and evaluated by your doctor.

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• Children and adolescents

Because of the lack of data on the use of the product in children and adolescents, Nebivolol STELLA Tablet 5mg is not recommended for use in them.

- Taking other medicines

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

Always tell your doctor if you are using or receiving any of the following medicines in addition to Nebivolol:

- Medicines for controlling the blood pressure or medicines used for heart problems (such as amiodarone, amlodipine, cibenzoline, clonidine, digoxin, diltiazem, disopyramide, felodipine, flecainide, guanfacin, hydroquinidine, lacidipine, lidocaine, methyldopa, mexiletine, moxonidine, nifedipine, nicardipine, nimodipine, nitrendipine, propafenone, quinidine, rilmenidine, verapamil).
- Sedatives and therapies used in the treatment of psychosis (a mental illness) e.g. barbiturates (also used for epilepsy), phenothiazine (also used for vomiting and nausea) and thioridazine.
- Medicines used to treat depression e.g. amitriptyline, paroxetine, fluoxetine.
- Medicines used for anaesthesia during an operation.
- Medicines used 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).

All of these medicines as well as nebivolol may influence the blood pressure and/or your heart function.

- Medicines used for treating excessive stomach acid or ulcers (antacid drug), e.g. cimetidine, you should take this medicine during a meal and take the antacid medicine between meals.
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have baby, ask your doctor for advice before taking this medicine.
- If your doctor has told you that you have intolerance to some sugars, contact your doctor before taking this medicine.

How to use Nebivolol STELLA Tablet 5mg

- How much to use

Always take this drug exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablet can be taken with or without food. The tablet is best taken with some water.

Treatment of raised blood pressure (hypertension)

- The recommended dose is 5 mg (one 5 mg tablet) 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 2.5 mg daily.
- The therapeutic effect on blood pressure becomes evident after 1-2 weeks of

treatment. Occasionally, the optimal effect is reached only after 4 weeks.

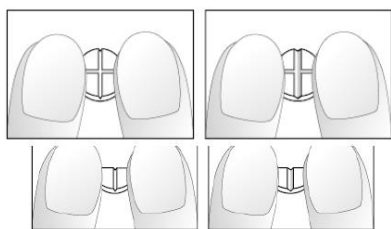
Treatment of chronic heart failure

- Your treatment will be started and closely supervised by an experienced physician.
- Your doctor will start your treatment with 1.25 mg per day. This may be increased after 1-2 weeks to 2.5 mg per day, then to 5 mg per day and then to 10 mg per day until the correct dose is reached for you. Your doctor will prescribe the dose that is right for you at each step and you should closely follow your doctor's instructions.
- The maximum recommended dose is 10 mg.
- You will need to be under the close supervision 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.
- You should not stop treatment abruptly as this can make your heart failure worse.
- Patients with serious kidney problems should not take this medicine.
- Take your medicine once daily, preferably at about the same time each day.
- If you have been told by your doctor to take $\frac{1}{4}$ (quarter) or $\frac{1}{2}$ (half) tablet daily, please refer to the instructions below on how to break Nebivolol STELLA Tablet 5mg cross-scored tablets.
 - Place the tablets onto a flat, hard surface (e.g. a table or worktop), with the cross score facing up.

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- Break the tablet by pushing it with the index fingers of both hands placed along one breakmark (Diagrams 1 and 2).
- Tablet quarters are obtained by breaking the halves in the same way (Diagrams 3 and 4).



Diagrams 1 and 2: Easy breaking of the Nebivolol STELLA Tablet 5mg cross-scored tablet in half.

Diagrams 3 and 4: Easy breaking of half of the Nebivolol STELLA Tablet 5mg cross-scored tablet into quarters.

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

- When to use it

Tablets may be taken with meals.

- How long to use it

You should take this drug for as long as your doctor continues to prescribe it.

- If you forget to use it

If you forget to take your medicine, but remember a little later that you should have taken it, take that day's dose as usual.

However, if a long delay has occurred (e.g. after 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 take too much (overdose)

If you accidentally take an overdose of this medicine, tell your doctor or pharmacist immediately. The most frequent symptoms and signs of a Nebivolol overdose are very slow heart beat (bradycardia), low blood pressure with possible fainting (hypotension), breathlessness such as in asthma (bronchospasm), and acute heart failure. You can take activated charcoal (which is available at your pharmacy) while you are waiting for your doctor to arrive.

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

While you are using Nebivolol STELLA Tablet 5mg

- Things you must do

- Take your medicine exactly as your doctor has told you.
- You should always talk to your doctor before stopping treatment with Nebivolol, whether you are taking it for high blood pressure or chronic heart failure.
- You should not stop Nebivolol treatment abruptly as this can temporarily make your heart failure worse.
- If it is necessary to stop Nebivolol treatment for chronic heart failure, the daily dose should be decreased gradually, by halving the dose in weekly intervals.

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

- Things you must not do

- Do not take too many tablets.
- Do not stop the treatment earlier than planned. Contact your doctor or pharmacist before stopping.
- Do not take any new medicines without consulting your doctor.

- Do not exceed the recommended dose.

- Things to be careful of

This medicine may cause dizziness or fatigue. If affected, do not drive or operate machinery.

Side effects

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

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

Common (may affect up to 1 in 10 people):

- Headache
- Dizziness
- Tiredness
- An unusual itching or tingling feeling
- 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 (difficulty in getting an erection)
- Feeling of depression
- Digestive difficulties (dyspepsia), 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 -scaly pink patches).

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The following side effects have been reported only in some isolated cases during treatment with this medicine:

- whole-body allergic reactions, with generalised skin eruption (hypersensitivity reactions)
- rapid-onset of swelling, especially around the lips, eyes, or of the tongue with sudden difficulties in breathing (angioedema).

- kind of skin rash notable for pale red, raised, itchy bumps of allergic or non-allergic causes (urticaria).

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

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

- slow heart beat
- dizziness
Common (may affect up to 1 in 10 people)
- worsening of heart failure
- low blood pressure (such as feeling faint when getting up too quickly)
- inability to tolerate this medicine
- a kind of light heart conduction disorder that affects the heart rhythm (1st degree AV-block)
- swelling of the lower limbs (such as swollen ankles)

If any of the side effects gets serious, or if you notice any side effects which are not listed in this leaflet, please tell your doctor or pharmacist.

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

Storage and Disposal of Nebivolol STELLA Tablet 5mg

- Storage

The expiry date of this pack is printed on the box.

Do not store above 30°C.

Keep all medicines out of reach of children.

Do not use Nebivolol STELLA Tablet 5mg if you notice any visible sign of deterioration.

- Disposal

Medicines should not be disposed of using wastewater or household waste. Ask your pharmacist how to dispose of medicines which are no longer required. These measures will help to protect the environment.

Product description

- What it looks like

Nebivolol STELLA Tablet 5mg appears as a white, round, biconvex tablet with cross score.

Dosage form: Tablets

Packaging size: Box of 3 blisters x 10 tablets.

- Ingredients

Active ingredient:

Nebivolol (as nebivolol hydrochloride) 5 mg

The other ingredients:

Lactose monohydrate

Pregelatinized starch

Povidone K30

Croscarmellose sodium

Crospovidone

Magnesium stearate

Colloidal anhydrous silica

MAL No.:

Manufacturer:

STELLAPHARM J.V. CO., LTD. - BRANCH 1

(A Joint Venture Company of Auxilto GmbH, Germany)

No. 40 Tu Do Avenue, Vietnam-Singapore Industrial Park, An Phu Ward, Thuan An Town, Binh Duong Province, Vietnam.

Product Registration Holder

Stadpharm Sdn. Bhd.

E-9-01, Oasis Square, Ara Damansara, No. 2, Jalan PJU 1A/7A, 47301 Petaling Jaya, Selangor Darul Ehsan, Malaysia.

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