Package leaflet: Information for the user

Nebivolol Teva 5 mg tablets
nebivolol

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 Nebivolol Teva is and what it is used for

Nebivolol Teva 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

Nebivolol Teva is used for the treatment of patients with:
- high blood pressure (hypertension)
- mild and moderate chronic heart failure in patients aged 70 or over, in addition to other therapies.

2. What you need to know before you take Nebivolol Teva

Do not take Nebivolol Teva
- if you are allergic to nebivolol or any of the other ingredients of this medicine (listed in section 6)
- if you have problems with your liver
- if you suffer from heart failure, which has just occurred or which has recently become worse, or if you are receiving treatment for circulatory shock due to acute heart failure by intravenous drip feed to help your heart work
- if you suffer from heart rhythm disorders (such as sick sinus syndrome including sino-atrial block)
- if you suffer from heart conduction disorders (such as second and third degree heart block and do not have a pacemaker)
- if you have asthma or have ever suffered from difficulty in breathing or wheezing
- if you have high blood pressure, flushing or diarrhoea caused by an untreated tumor of the adrenal medulla (phaeochromocytoma)
- if you have a metabolic disorder where there is a change in the acid/base balance of the body (metabolic acidosis)

- if you have a slow heart rate (less than 60 beats per minute before you start taking this medicine)
- if you have low blood pressure (systolic blood pressure less than 90 mmHg)
- if you have poor circulation in the arms or legs

Warnings and precautions
Talk to your doctor before taking Nebivolol Teva.

Inform your doctor if you have or develop one of the following conditions:
- if you are to have an operation requiring an anaesthetic, always inform your anaesthetist that you are on Nebivolol Teva before being anaesthetised
- untreated chronic heart failure
- abnormally slow heart rate
- if you suffer from circulation problems in the arms or legs (such as Raynaud's disease or syndrome, intermittent claudication), cramp-like pains when walking
- if you suffer from first degree heart block
- if you suffer from heart chest pain at rest that occurs in cycles (Prinzmetal's angina)
- if you are diabetic, as nebivolol may hide the symptoms of low blood sugar (hypoglycaemia)
- if you suffer thyroid problems, as nebivolol may hide the symptoms of high heart rate (tachycardia)
- If you have patches of thickened and sore skin (psoriasis)
- If you suffer from allergic reactions, as nebivolol may increase the severity of these reactions
- In patients with chronic obstructive pulmonary disorders, beta-adrenergic antagonists should be used with caution as airway constriction may be aggravated.
- if you suffer from prolonged breathing problems.

If you have serious kidney problems, do not take Nebivolol Teva to treat 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).

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

Other medicines and Nebivolol Teva

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

Talk to your doctor if you are taking any of the following:
- Medicines for controlling the blood pressure or medicines for heart problems (such as amiodarone, amlodipine, cibenzoline, clonidine, digoxin, diltiazem, disopyramide, felodipine, flecainide, guanfacin, hydroquinidine, lacidipine, lidocaine, methyldopa, mexiletine, moxonidine, nicardipine, nifedipine, nimodipine, nitrendipine, propafenone, quinidine, rilmenidine, verapamil).
- Sedatives and therapies for mental illness (psychosis) e.g. barbiturates (also used for epilepsy), phenothiazines (also used for vomiting and nausea) and thioridazine.
- Medicines for depression e.g. amitriptyline, paroxetine, fluoxetine.
- 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)

All these drugs as well as Nebivolol Teva may influence the blood pressure and/or heart function.

- Medicines for treating excessive stomach acid or ulcers (antacid drug): You should take Nebivolol Teva during a meal and the antacid drug between meals.

Nebivolol Teva with food and drink

Please see section 3.

Pregnancy and breast-feeding

Nebivolol Teva should not be used during pregnancy, unless clearly necessary.
It is not recommended for use while breast-feeding.

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.

Driving and using machines

Nebivolol Teva may cause dizziness and fatigue. If this happens to you, do not drive or operate machinery.

Nebivolol Teva contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Nebivolol Teva contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Nebivolol Teva

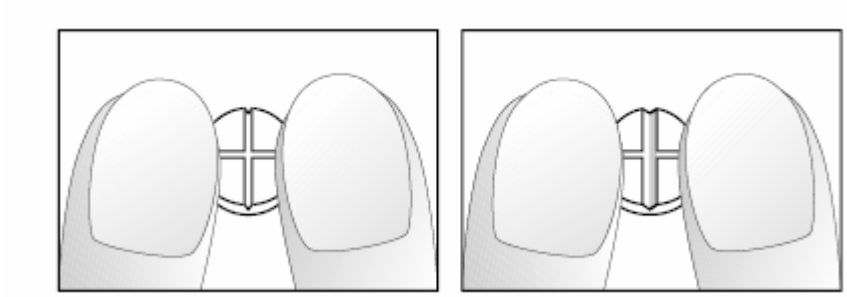
Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Method of administration:

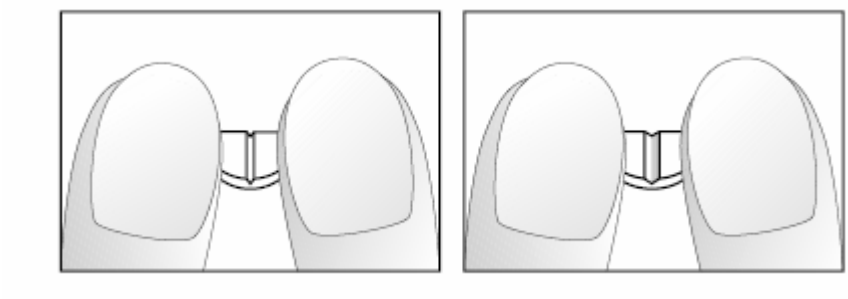
The tablet should be swallowed with a sufficient amount of fluid (e.g. one glass of water). The tablet can be taken with or without food. The tablet can be divided into equal halves and quarters.

If you have been told by your doctor to take ¼ (quarter) or ½ (half) tablet daily, please refer to the instructions below on how to break Nebivolol Teva cross-scored tablets.

- Place the tablets onto a flat, hard surface (e.g. a table or worktop), with the cross score facing up.
- 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 5 mg cross-scored tablet in half.



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

Raised blood pressure (hypertension)

Adults
The recommended dose is 5 mg (one tablet) daily, preferably at the same time of the day.

The blood pressure lowering effect becomes evident after 1-2 weeks of treatment. Occasionally, the optimal effect is reached only after 4 weeks.

Patients with kidney problems
If you have kidney problems, the recommended starting dose is 2.5 mg daily (half a tablet). If needed your doctor will increase your daily dose to 5 mg.

Elderly
If you are over 65 years old, the recommended starting dose is 2.5 mg daily (half a tablet). If needed, your doctor will increase your daily dose to 5 mg.

Use in children and adolescents
Nebivolol Teva is not recommended for children and adolescents below 18 years.

Chronic heart failure

Adults
- Your treatment will be started and closely supervised by an experienced physician.
- Your doctor will start your treatment with ¼ (quarter) tablet per day. This may be increased after 1-2 weeks to ½ (half) tablet per day, then to 1 tablet per day and then to 2 tablets 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 his/her instructions.
- The maximum recommended dose is 2 tablets (10mg) a day.
- 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 of day.

Use in children and adolescents
Nebivolol Teva is not recommended for children and adolescents below 18 years.

Combination with other medicines
Your doctor may decide to combine Nebivolol Teva with other medicines to treat your condition.

If you take more Nebivolol Teva than you should
If you (or someone else) swallow a lot of the tablets all together or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor 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.
Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Nebivolol Teva
If you forget a dose of Nebivolol, 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. for 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. Repeated skipping, however, should be avoided.

If you stop taking Nebivolol Teva
Do not stop taking Nebivolol Teva without talking to your doctor, whether you are taking it for high blood pressure or chronic heart failure. You should not stop Nebivolol Teva treatment abruptly as this can temporarily make your heart failure worse. If it is necessary to stop Nebivolol Teva treatment for chronic heart failure, the daily dose should be decreased gradually, by halving the dose, at weekly intervals.

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 Nebivolol Teva 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 heart beat or other heart complaints
- low blood pressure
- cramp-like leg pains on walking
- abnormal vision
- impotence (erectile dysfuntion)

- breathlessness such as in asthma, due to sudden cramps in the muscles around the airways (bronchospasm)
- indigestion, gas in stomach or bowel, vomiting
- itching, skin rash
- nightmares
- feelings of depression

Very rare (may affect up to 1 in 10,000 people):
- fainting
- worsening of psoriasis (skin rash).

The frequency of the following side effects is not known:
- 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);
- 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 side effects (may affect more than 1 in 10 people):
- slow heart beat
- dizziness

Common side effects (may affect up to 1 in 10 people):
- 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 AV-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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nebivolol Teva

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 blister foil and carton. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.

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 Nebivolol Teva contains

The active substance is nebivolol (as hydrochloride). Each tablet contains 5 mg nebivolol equivalent to 5.45 mg of nebivolol hydrochloride.

The other ingredients are lactose monohydrate, croscarmellose sodium, silica colloidal anhydrous, macrogol 6000 and magnesium stearate.

What Nebivolol Teva looks like and contents of the pack

Round, white, biconvex tablet with a diameter of 9 mm, cross-scored on one side and marked with 'N 5' on the other side.
Tablets are provided in clear, colourless PVC/PE/PVdC/Al blisters or PVC/PE/PVdC/Al unit dose blisters.
Pack sizes: 7, 8, 10, 14, 15, 20, 28, 30, 50, 56, 60, 90, 98, 100, 500 and 50 x 1 unit dose blisters (hospital pack).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Teva Pharma B.V.
Swensweg 5,
2031GA Haarlem,
The Netherlands.

Manufacturers
Balkanpharma Dupnitsa AD, 3 Samokovsko Shosse Str., Dupnitsa 2600, Bulgaria

Actavis Ltd, BLB 015-016, Bulebel Industrial Estate, Zejtun ZTN 3000, Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Nebivolol Teva 5 mg tabletten
Bulgaria: Nebivolol Teva 5 mg tablets
Estonia: NEBIPHAR
Hungary: Nebivolol-Teva 5 mg tabletta
Ireland: Nebivolol Teva 5 mg Tablets
Italy: Nebivololo Teva Italia 5 mg compresse
Latvia: Nebiphar 5 mg tabletes
The Netherlands: Nebivolol Teva 5 mg , tabletten
Spain: Nebivolol Teva 5 mg comprimidos EFG

This leaflet was last revised in 05/2021.