

Package leaflet: Information for the patient
Bravylol 5 mg tablets

Nebivolol (as neбиволol hydrochloride))

Read all of this leaflet carefully before you start taking this medicine.

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

Remember - this medicine is only for you!

What is in this leaflet:

1. What Bravylol is and what it is used for
2. Before you take Bravylol
3. How to take Bravylol
4. Possible side effects
5. How to store Bravylol
6. Other information

1. What Bravylol is and what it is used for

The name of your medicine is Bravylol, the active ingredient is neбиволol hydrochloride. Each tablet contains 5 mg of neбиволol hydrochloride.

Bravylol is an antihypertensive drug (β -receptor blocker). It is used for:

- treatment of essential hypertension;
- treatment of mild and moderate chronic heart failure in patients aged 70 or over, in addition to other therapies.

2. Before you take Bravylol

Do not take Bravylol:

- if you are allergic to neбиволol hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you have liver function disorder;
 - if you are pregnant or breast-feeding;
- low blood pressure, serious circulation problems in the arms or legs, very slow heartbeat (less than 60 beats per minute) or any other heart diseases;
- 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);
- untreated phaeochromocytoma, a tumour located on top of the kidneys (in the adrenal glands);
- a metabolic disorder (metabolic acidosis), for example, diabetic ketoacidosis.

Nebivolol should not be taken by children and adolescents!

Take special care with Bravylol

Before you start taking the tablets, tell your doctor if you are pregnant, trying to become pregnant or breast-feeding.

Inform your doctor if you:

- abnormally slow heartbeat (heart rate below 50-55 beats / minute at rest and / or symptoms such as dizziness, weakness, unstable gait);
- heart disease: such as angina (chest pain) or other heart problems;
- 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); however, sweating, which may be a sign of low blood sugar, will persist;
- 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: Nebivolol should only be used after a careful benefit / risk assessment.

Your doctor will decide if you should take this medicine and if you need to change the dose.

Other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This applies in particular to the following medicinal products:

- 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);
- during treatment with Bravylol should not be administered intravenously verapamil;
- medicines for cardiac arrhythmias (cardiac arrhythmias) such as quinidine, hydroquinidine, amiodarone, cibenzoline, flecainide, disopyramide, lidocaine, mexiletine, propafenone;
- medicines for anxiety, e.g. baritrates, phenothiazines;
- medicines for depression, e.g. amitriptyline, trazodone, paroxetine, fluoxetine, thioridazine;
- medicines for asthma, blocked nose or certain eye disorders such as glaucoma (increased pressure in the eye) or dilation (widening) of the pupil;
- anesthetics: always inform the anesthesiologist before anesthesia that you are taking nebivolol;
- drugs to increased acidity in the stomach (eg. cimetidine) - should take nebivolol during a meal, and the antacid - between meals;
- dextromethorphan (in some cough medicines).

Bravylol with food and drinks

The tablets can be taken with food. It is recommended that the prescribed daily dose is always taken at the same time of day. The tablet should be taken with a sufficient amount of liquid (eg 1 glass of water).

Pregnancy and breast-feeding

Bravylol should not be used during pregnancy and breast-feeding.

Ask your doctor or pharmacist before taking any medicine during pregnancy or breastfeeding!

Driving and using machines

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

Bravylol contains lactose

This product 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 Bravylol

Always take Bravylol exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Treatment of raised blood pressure (hypertension)

The usual dose is 1 tablet per day. (5 mg nebivolol). The therapeutic effect on blood pressure becomes evident after 1-2 weeks of treatment. Occasionally, the optimal effect is reached only after 4 weeks.

Elderly patients and patients with a kidney disorder will usually start with ½ (half) tablet daily.

Treatment of chronic heart failure

Bravylol treatment should be started gradually, and depending on tolerability, the low dose of 2.5 mg once daily may be increased every 14 days by 2.5 mg nebivolol to doses of 10 mg nebivolol once daily until the appropriate dose is reached.

The maximum recommended dose is 2 tablets (10mg) a day.

When the first dose of Bravylol is given, as well as when the dose is increased, a sharp drop in blood pressure may occur. Therefore, these patients should be under close supervision for about 2 hours after the first dose of nebivolol and as the dose is increased to avoid a sharp drop in blood pressure.

The duration of treatment is determined by your doctor. Treatment of high blood pressure can last a lifetime, and the blood pressure lowering effect is maintained with long-term treatment.

If you take more Bravylol than you should

If you accidentally take an overdose of this medicine, tell your doctor or pharmacist immediately.

If you forget to take Bravylol

If you forget a dose of Bravylol, 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. a day), so wait for the next intake. **Do not take a double dose.**

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

4. Possible side effects

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

When used correctly, side effects with Bravylol are mild to moderate and rare.

When Bravylol is used for the treatment of raised blood pressure, the following side effects may occur (in less than 1 in 100 patients and more than 1 in 1000 patients treated with this medicine): headache, dizziness, skin rash, itchiness, shortness of breath, constipation, nausea, diarrhoea, fatigue, swollen hands or feet, pain or cramps when walking, abnormal vision, impotence, slow heartbeat or other heart complaints, difficulty swallowing, tightness in the throat, nightmares.

In a clinical study for chronic heart failure, the following side effects were seen: slow heart beat, dizziness, worsening of heart failure, low blood pressure (such as feeling faint when getting up quickly), inability to tolerate this medicine, irregular heartbeat, swelling (eg swollen ankles).

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

5. How to store Bravylol

Keep this medicine out of the sight and reach of children.
Store below 25°C.

Do not use this medicine after the expiry date which is stated on the carton label and blister foil after EXP.

Do not use Bravylof if you notice any visible changes in the tablets.

Do not throw any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Other information

What Bravylof contains

- The active substance is nebivolol (nebivolol hydrochloride).
- The other ingredients are: lactose monohydrate, croscarmellose sodium, maize starch, hypromellose, microcrystalline cellulose, silica colloidal anhydrous and magnesium stearate.

What the package contains

Each pack of Bravylof tablets contains 3 or 9 blisters of 10 tablets with a score line.

Marketing Authorisation Holder and Manufacturer

Tchaikapharma High Quality Medicines Inc.
1 G. M. Dimitrov Blvd, Sofia 1172, Bulgaria

For any information about this medicine, please contact the local representative of the Marketing Authorization Holder:

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