In this leaflet:

1. What Nebivolol 5mg tablets are and what they are used for
2. Before you take
3. How to take
4. Possible side effects
5. How to store
6. Further information

What Nebivolol 5mg tablets are and what they are used for

Nebivolol 5mg tablets belong to a group of medicines known as beta-blockers. They work by blocking the activity of specific proteins in the heart, lungs, pancreas, liver, and blood circulation system.

Nebivolol 5mg tablets are used to:

- high blood pressure (hypertension)
- chronic heart failure in patients aged 70 years or older.

Before you take

Do not take Nebivolol 5mg tablets if you:

- are allergic (hypersensitive) to nebivolol or any of the other ingredients of Nebivolol 5mg tablets.
- suffer from liver problems.
- have low blood pressure or poor circulation in the arms or legs.
- have a very slow heart beat (less than 60 beats per minute).
- have heart rhythm problems.
- have the condition heart failure which has just occurred or which has recently become worse.
- have asthma or wheezing (now or in the past).
- have been told by your doctor that you have a tumour in your adrenal gland (which is located on top of the kidneys) (the medical term for this is an untreated phaeochromocytoma).
- have metabolic acidosis such as diabetic ketoacidosis.

If you are unsure, contact your doctor.

Take special care with Nebivolol 5mg tablets:

Tell your doctor before you start to take this medicine if you:

- notice that your heart rate is abnormally slow or you experience shortness of breath or dizziness.
- have ischaemic heart disease such as angina (chest pain).
- have been told you suffer from any of the following conditions:
  - poor blood circulation which makes the toes and fingers numb and pale (Raynaud’s disease).
  - a type of chest pain due to spontaneously occurring heart cramp called Prinzmetal angina.
  - pain, tension and weakness in the legs when walking which is relieved by rest (intermittent claudication).
  - a persistent obstruction of your airways such as chronic bronchitis.
  - diabetes, as it can hide the warning signs of low sugar levels.
  - over activity of the thyroid gland (hyperthyroidism).
  - a skin condition known as porphyria.
  - impairment of the electrical conduction of signals in the heart (first degree heart block).
  - are being treated with any other drugs which lower your blood pressure.

If you need to have an operation and need an anaesthetic, it is particularly important that verapamil is not injected into a vein during treatment with nebivolol.

Clenidone, guanethidine, methyldopa and omeprazole, which are used to treat high blood pressure.

Quinidine, hydroquinidine, amiodarone, clenodine, flecaidine, disopyramide, lidocaine, mexiletine and propafenone, which are used to treat cardiac arrhythmias (irregular heartbeat).

Barbiturates and phenytoin, which are used to treat anxiety and seizures in epilepsy.

Amitriptyline, trazodone, paroxetine, fluoxetine and omeprazole, which are used to treat depression.

Asthma medicines, medicines for blocked nose (e.g. pseudoephedrine) or for certain eye disorders such as glaucoma (increased pressure in the eye) or discoloration of the pupil.

Medicines for diabetes (insulin and medicines for oral use).

Anasthetics. Always inform your anaesthetist that you are on nebivolol before being anaesthetized.

Antacids (e.g. sodium bicarbonate) which are used to treat excessive stomach acid. If you are being treated for excessive stomach acid, you should take nebivolol before a meal, and the antacid drug between meals.

Dietomeorphan (found in cough medicines).

Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) such as ibuprofen and diclofenac, which are used to treat certain types of pain and inflammation.

Baclofen (a muscle relaxant).

Amoxicillin (used to treat some infections), chloroquine (used to treat malaria) and terbinafine (for fungal infections).

Bupropion for smoking cessation.

Taking Nebivolol 5mg tablets with food and drink

Nebivolol can be taken with or without food unless you take antacids (see “Taking other medicines”). The tablet should be swallowed with a glass of water or other liquid.

Pregnancy and breast-feeding

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

Driving and using machines

Nebivolol may cause tiredness and/or dizziness and if you are affected you should not drive or use any machines or tools.

Sugar intolerance

This medicine 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.

How to take

Always take Nebivolol 5mg tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Treatment of high blood pressure (hypertension)

The usual dose is one tablet (5mg) daily, although elderly patients and patients with kidney problems may begin treatment on a lower dose.

The blood pressure lowering effect may take up to 1-2 weeks of treatment to become evident. Occasionally, the optimal effect is only reached after 4 weeks.

Treatment of chronic heart failure

The usual initial dose is 1.25mg daily. This may be increased after 1-2 weeks to half a tablet daily (0.75mg) and then to 1 tablet daily (5mg). This may be further increased to a maximum recommended dose of 2 tablets daily (10mg).

Your doctor may reduce your dose if necessary. Every time your dose is changed, your doctor will monitor you for approximately two hours.

Nebivolol 5 mg - PIL UK

Item no: BBA1131

Dimensions: 180x350

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Like all medicines, Nebivolol 5mg tablets can cause side effects, although not everybody gets them.

Hypertension

The side effects reported in people taking nebivolol for hypertension are listed below:

- whole-body allergic reaction, with generalised skin eruption (hypersensitivity reactions)

Very rare Side Effects (that affect fewer than 1 person in every 10,000 treated):

- fainting
- worsening of psoriasis (a skin disease - scaly pink patches)
- rapid-onset swelling, especially around the lips, eyes, or of the tongue with sudden difficulty breathing (angioedema)

Uncommon Side Effects (that affect more than 1 person in every 1000 but fewer than 1 person in 100):

- Low blood pressure
- Cramps like leg pains on walking
- Abnormal vision
- Impotence
- Depressive feelings
- Indigestion
- Gas in stomach or bowel
- Vomiting
- Skin rash
- Tightness in the throat
- Nightmares
- Itching

Common Side Effects (that affect more than 1 person in every 100 but fewer than 1 person in every 10 treated):

- Headache
- Dizziness
- Tiredness
- An unusual itching or tingling feeling
- Diarrhoea
- Constipation
- Nasal (nose) stuffiness
- Shortness of breath
- Swollen hands or feet

Chronic Heart Failure

The side effects reported in people taking nebivolol for chronic heart failure are listed below:

- Worsening of heart failure
- Low blood pressure (with symptoms such as feeling faint when you get up quickly)
- Inability to tolerate the medicine
- Irregular heartbeat
- Swollen legs, ankles, or feet

Very Common Side Effects (that affect more than 1 person in every 10 treated):

- Fainting

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

Possible Side Effects

1. How to store

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use Nebivolol 5mg tablets after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

2. Further Information

What Nebivolol 5mg tablets contain

The active substance is nebivolol hydrochloride corresponding to 5mg nebivolol.

The other ingredients are microcrystalline cellulose, magnesium stearate, croscarmellose sodium, macrogol 6000, and lactose monohydrate.

What Nebivolol 5mg tablets look like and contents of the pack

Round, white, biconvex tablets with a cross-score on one side and marked “N5” on the other. The tablets can be divided into equal quarters.

Pack size: 28 tablets

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