

NEBILET™

(nebivolol hydrochloride) oral tablets

PATIENT INFORMATION LEAFLET

INFORMATION FOR PEOPLE TAKING NEBILET™ ORAL TABLETS

Before you start to take your medicine, please read this leaflet carefully all the way through as it contains important information. This leaflet does not contain the complete information. If there is anything that you do not understand or if you need further information or advice, you should ask your doctor or pharmacist. This leaflet applies to Nebilet tablets. Please do not throw it away until you have finished taking the full course of your medicine. You may need to refer to it again.

What is your medicine?

The name of your medicine is Nebilet and its active ingredient is nebivolol hydrochloride. Nebilet tablets are white, round, cross-scored tablets. Each tablet contains nebivolol hydrochloride corresponding with 5 milligrams of nebivolol. The tablets also contain polysorbate, hypromellose, lactose, maize starch, croscarmellose sodium, microcrystalline cellulose, colloidal silica and magnesium stearate. The licence of this medicine is held by Berlin Chemie AG, Glienicke Weg 125, D-12489, Berlin, Germany, under licence of Janssen Pharmaceutica N.V., Beerse- Belgium. Nebilet tablets are manufactured by Berlin Chemie AG, Glienicke Weg 125, D-12489, Berlin, Germany.

What is your medicine used for?

Nebilet is used to treat an increased blood pressure (hypertension). Nebilet is also used to treat chronic heart failure in patients aged 70 or over.

REMEMBER - This medicine has been prescribed for you only. Never give it to anyone else. It may harm them even if their symptoms are the same as yours.

WHAT SHOULD YOU KNOW BEFORE YOU START YOUR TREATMENT BEFORE TAKING ANY MEDICINE - always inform your doctor if you are pregnant, think you might be pregnant or are trying to become pregnant.

When not to use your medicine

Do not use Nebilet if you are allergic to any of its ingredients, which can be found under "What is Nebilet?".

Do not use Nebilet if you are pregnant or breast-feeding.

Do not use Nebilet if you have one or more of the following disorders:

- liver function disorder;
 - low blood pressure, poor circulation in the arms or legs, very slow heartbeat (less than 60 beats per minute) or certain other heart problems;
 - your heart failure has just occurred or worsened recently, or you are receiving treatment into a vein (by intravenous "drip") to help your heart work;
 - asthma or wheezing (now or in the past);
 - certain tumours in the adrenal glands;
 - a metabolic disorder (metabolic acidosis) characterized by too much acid in your body (and blood).
- If in doubt, contact your doctor or pharmacist.

SPECIAL PRECAUTIONS

Pregnancy and Nebilet

It is not yet clear whether Nebilet can be harmful during pregnancy. To date, animal studies have not shown any harmful effects.

Nebilet should not be used during pregnancy. If you are pregnant or plan to become pregnant while on Nebilet, you should discuss with your doctor whether you can take Nebilet.

If you do find that you are pregnant after starting a course of Nebilet tablets, stop taking it and tell your doctor straight away.

Breast-feeding and Nebilet

It is not known whether the active ingredient of Nebilet could be present in your milk. Hence, you should not use Nebilet while breast-feeding. If necessary, consult your doctor.

Elderly and Nebilet

When you are above 65 years of age, your doctor will in principle start your treatment with 1/2 tablet if you are taking Nebilet for increased blood pressure (See also "How should you take Nebilet").

Children, Adolescents and Nebilet

Because nothing is known about its effect on children and adolescents, Nebilet should not be given to them.

Kidney problems and Nebilet

Tell your doctor if you have a renal disorder. In principle, your doctor will start your treatment with 1/2 tablet daily if you are taking Nebilet for increased blood pressure. Afterwards, your doctor may decide to prescribe a higher dose.

Other precautions

In certain situations, Nebilet should be used with greater caution. Inform your doctor if you have or develop one of the following problems:

- abnormally slow heartbeat or other heart problems;
- poor circulation in the arms or legs;
- prolonged breathing problems;
- diabetes: Nebilet has no effect on blood sugar, but it could mask the signs of a low sugar level (nervousness, trembling, faster heartbeat). Sweating as a sign, however, does not disappear;
- increased production of thyroid hormone (thyrotoxicosis): abrupt withdrawal of Nebilet may increase your heart beat;
- allergy: Nebilet may intensify your reaction to pollen or other substances you are allergic to;
- psoriasis.

In these cases, your doctor may need to adapt your treatment or check you more often.

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

Driving or operating machinery

From time to time, dizziness or tiredness may occur as a side-effect. It is wise to take this into account while driving or operating machinery.

Other medicines and Nebilet

Always inform your doctor or pharmacist if you are using or intend to use other medicines. Certain medicines cannot be used at the same time, while other drugs require specific changes (in the dose, for example).

Always inform your doctor or pharmacist if you are using or receiving any of the following medicines in addition to Nebilet:

- certain medicines for heart or blood disorders, such as other drugs for high blood pressure e.g. verapamil, diltiazem, quinidine, hydroquinidine, cibenzoline, flecainide, disopyramide, lidocaine, mexiletine, propafenone, clonidine, guanfacin, moxonidine, methyl dopa, rilmenidine, amlodipine, felodipine, lacidipine, nifedipine, nicardipine, nimodipine, nitrendipine. During Nebilet treatment, drugs with verapamil should not be injected into a vein.
 - drugs for anxiety e.g. barbiturates, phenothiazine,
 - certain drugs for depression eg. amitriptyline, trazodone, paroxetine, fluoxetine, thioridazine, quinidine, which could intensify the effect of Nebilet.
 - certain drugs for asthma, blocked nose or certain eye disorders (so-called "sympathomimetics"), which may weaken the effect of Nebilet.
 - drugs used for diabetes (insulin and the medicines to be taken by mouth); see also "Other precautions".
 - anaesthetics: always inform your anaesthetist that you are on Nebilet before being anaesthetized.
- If, in addition to Nebilet, you are using a drug for excessive stomach acid (e.g. cimetidine), you should take Nebilet during the meal, and the antacid drug between meals.
- dextromethorphan (found in cough medicines).

HOW MUCH SHOULD YOU TAKE?

Your doctor or pharmacist has told you how much Nebilet you should take. Always take the prescribed amount, which generally is 1/4 to 2 tablets per day. Elderly and patients with a renal disorder start in principle with 1/2 tablet daily for the treatment of increased blood pressure or 1/4 tablet daily for chronic heart failure.

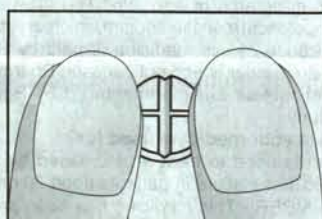
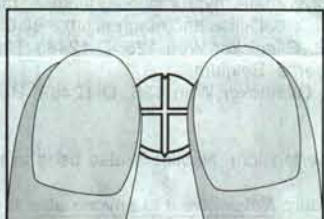
In hypertension usually it takes up to 3 weeks before the effect of Nebilet is maximal.
In chronic heart failure the initial up-titration should be done according to the following steps at 1-2 weekly intervals based on patient tolerability:
1.25 mg nebivolol, to be increased to 2.5 mg nebivolol once daily, then to 5 mg once daily and then to 10 mg once daily.
The maximum recommended dose is 10 mg nebivolol once daily.
Your doctor may decide to combine Nebilet with other medicines for your condition.

HOW TO USE YOUR MEDICINE?

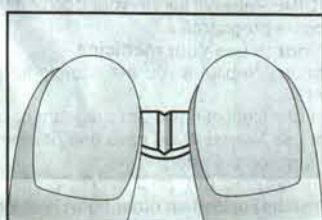
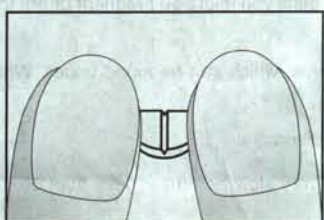
- It is important that you should take your medicine daily, preferably at about the same time.
- You can take Nebilet before, during or after the meal, but also independently of the meal. It is best taken with some water or another liquid.

If you have been told by your doctor to take 1/4 or 1/2 tablet daily, please refer to the instructions below on how to break Nebilet 5 mg 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.

WHAT TO DO IF YOU FORGET TO TAKE YOUR MEDICINE?

If you have forgotten your medicine, simply go on taking the medicine the next day at the usual time and skip the forgotten dose. Repeated skipping however is to be avoided.

IF YOU TAKE TOO MUCH OF YOUR MEDICINE

Contact your doctor immediately if you or someone else has taken too much Nebilet. An abnormally slow heartbeat, decreased blood pressure, breathing difficulties and sudden heart problems may occur.

Before a doctor arrives, you can take (or give) activated charcoal (available at the pharmacist's or a drugstore), which absorbs any medicine left in the stomach.

IF YOU THINK YOUR MEDICINE MAKES YOU FEEL ILL

- The most frequent undesired effects when used for raised blood pressure are headache, dizziness, tiredness, an unusual itching or tingling feeling, diarrhoea, constipation, nausea, shortness of breath and swollen hands or feet.
- The following effects can occur but are rare when used for raised blood pressure: slow heartbeat or other heart complaints, low blood pressure, walking problems due to narrowing of the blood vessels in the legs, decreased eyesight, impotence, depressive feelings, digestive disorders, gas, vomiting, skin rash, suffocating feeling due to narrowing of the airways, or nightmares.
- In clinical studies for chronic heart failure, the most common side-effects seen were slow heart beat and dizziness.

Contact your doctor if any of these undesired effects bother you and certainly if you experience any of the effects mentioned in "Special Precautions". Inform your doctor or pharmacist of any other unexpected or unusual undesired effects.

HOW TO STORE YOUR MEDICINE

Always keep Nebilet and this information in the package in which it comes at the pharmacy. In this way, you can read the information again. There are no special storage instructions.
Keep Nebilet out of the reach and sight of children.

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MENARINI INTERNATIONAL