

## NEBILET® Tablets

neбиволол hydrochloride

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about NEBILET. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet.

#### Speak to your pharmacist or doctor to obtain the most up to date information on this medicine.

You can also download the most up to date leaflet from [www.menarini.com.au](http://www.menarini.com.au).

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NEBILET against the benefits they expect it will have for you.

#### If you have any concerns about taking this medicine, ask your doctor or pharmacist.

#### Keep this leaflet with the medicine.

You may need to read it again.

#### What NEBILET is used for

NEBILET is used to treat:

- high blood pressure (essential hypertension) or,
- chronic heart failure. It is usually used in combination with other medicines.

This medicine belongs to a group of medicines called beta-blockers.

#### High Blood Pressure (Hypertension):

NEBILET can be used to treat high blood pressure. It works by blocking the transmission of messages to the beta receptors in the heart which slows down the activity of the heart. It also relaxes the blood vessels and reduces the resistance that the heart has to pump against. The blood pressure lowering effects occur after 1 to 2 weeks, although it may take up to 4 weeks for the full effect to occur.

#### Chronic Heart Failure:

NEBILET can also be used to treat chronic heart failure. It slows down the heart rate and makes it beat more regularly.

It also reduces the pressure the heart has to pump against and therefore reduces the amount of work that the heart has to do.

This improves the symptoms of chronic heart failure, and reduces the likelihood of you being hospitalized and/or dying from your heart condition.

#### Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is/is not addictive.

It is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

#### Before you take NEBILET

##### When you must not take it

##### Do not take NEBILET if you have an allergy to:

- any medicine containing neбиволол hydrochloride

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

##### Do not take NEBILET if you:

- have liver problems
- have acute heart failure or cardiogenic shock, a serious heart condition causing low blood pressure
- have a history of slow heart rate or uneven heart beating
- have certain other heart conditions
- have asthma, bronchitis or other lung disease with tightening of the airways
- have untreated phaeochromocytoma, a rare tumour of the adrenal gland
- have metabolic acidosis, where there is too much acid in the blood
- have hypotension, low blood pressure
- have a severe blood vessel disorder causing poor circulation in the arms and legs.

##### Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

##### Do not breast-feed if you are taking this medicine.

The active ingredient in NEBILET passes into breast milk and there is a possibility that your baby may be affected.

##### Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

##### Do not take this it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering or the tablets do not look quite right.

If it has expired or is damaged, return it to your pharmacist for disposal.

##### If you are not sure whether you should start taking this medicine, talk to your doctor.

##### Before you start to take it

##### Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

##### Tell your doctor if you have or have had any of the following medical conditions:

- low blood pressure or poor circulation
- a slow heart beat, lower than 60 beats per minute
- asthma or breathing difficulties
- angina, chest pain or any other heart problems, or your heart failure has just occurred or worsened recently
- diabetes
- a history of psoriasis, a skin disease with thickened patches of red skin, often with silvery scales
- a severe blood vessel disorder causing poor circulation in the arms and legs
- thyroid disorders
- liver problems

- kidney problems
- phaeochromocytoma, a rare tumour of the adrenal gland
- a lactose intolerance

##### Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

##### Tell your doctor if you plan to have surgery, even at the dentist's.

Your surgeon and anaesthetist should know well ahead of the date of your surgery so they can allow for your condition and medications.

##### If you have not told your doctor about any of the above, tell him/her before you start taking NEBILET.

##### Taking other medicines

##### Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and NEBILET may interfere with each other. These include:

- those used to treat irregular or abnormal heartbeat (eg. quinidine, flecainide, disopyramide, lignocaine, mexiletine, amiodarone)
- those used to treat high blood pressure (eg. clonidine)
- calcium channel blockers for high blood pressure or heart problems (eg. verapamil, diltiazem)
- insulin and tablets used to treat diabetes
- those used to treat depression and anxiety (eg. phenelzine, tranlycypromine, paroxetine, sertraline, sedatives, phenothiazine)
- those used to treat excessive stomach acid (eg. cimetidine).

##### You should take NEBILET® during a meal, and the antacid between meals.

- digoxin, a medicine used to treat heart failure
- drugs used to treat asthma, blocked nose or certain eye disorders such as glaucoma or dilation of the pupil
- dextromethorphan, an ingredient in cough medicines
- anaesthetics
- other beta-blocker medicines, including beta-blocker eye drops

These medicines may be affected by NEBILET or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

#### How to take NEBILET

##### You should only start taking NEBILET under the direct supervision of your doctor.

##### Your doctor will tell you how much you should take, when and how often.

##### Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

**Do not stop taking NEBILET without speaking to your doctor first.**

You should not stop treatment with NEBILET suddenly as this can worsen your condition.

#### *How much to take*

##### **High Blood Pressure (Hypertension):**

For the treatment of high blood pressure, the usual starting dose is one 5mg tablet each day. Your doctor may start you on a lower dose of NEBILET.

##### **Chronic Heart Failure:**

For the treatment of chronic heart failure, your doctor will start you on a low dose of NEBILET, and gradually increase the dose depending on how you respond to this medicine.

The usual starting dose is one 1.25mg tablet each day. Your doctor will gradually increase your dose stepwise over a number of weeks, one tablet at a time until you reach the best dose for you.

The highest dose you should take is 10mg each day.

When you take NEBILET® for the first time, and whenever your doctor increases your dose, you should be observed by a doctor for at least 2 hours until the effect of the medicine on you is known.

Your doctor may reduce your dose if necessary, and you should not stop treatment abruptly as this can worsen your condition.

#### *How to take it*

**Swallow the tablets whole with a full glass of water.**

**Do not crush or chew the tablets**

#### *When to take it*

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food or with food.

**If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of NEBILET.**

#### *How long to take it*

**Continue taking your medicine for as long as your doctor tells you.**

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

#### *If you forget to take it*

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose that you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

#### *If you take too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766 in New Zealand) for advice, or go to Emergency at the nearest hospital, if you think that you or anyone else may have taken too much NEBILET.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may include feeling faint or fainting, and shortness of breath. Your blood pressure may drop too far and your heart rate might slow down too much. In extreme cases, serious heart and lung problems may occur.

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#### **While you are using NEBILET**

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##### *Things you must do*

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking NEBILET.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, even at the dentist, tell the surgeon, anaesthetist or dentist that you are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may check your eyes, thyroid, lipid and blood glucose levels.

**If you have any medical test, tell your doctor that you are taking NEBILET.**

This medicine may affect the results of some tests.

**Tell your doctor if you believe that NEBILET® is not helping your condition.** Your doctor may need to change the dose.

**Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.** Your doctor may think it is not working effectively and change your treatment unnecessarily.

**If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.**

NEBILET may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar, called hypoglycaemia, such as fast heart beat. NEBILET may make hypoglycaemia last longer. Your dose of diabetic medicines, including insulin, may need to change.

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

You may feel light-headed or dizzy when you begin to take NEBILET. This is because your blood pressure has fallen suddenly.

Standing up slowly, especially when you get up from bed or from sitting, will help your body adjust to the change in position and blood pressure. If this problem continues or gets worse, tell your doctor.

**Make sure you drink enough water during exercise and in hot weather when you are taking NEBILET, especially if you sweat a lot.** If you do not drink enough water while taking this medicine you may feel faint or light-headed. This is because your blood pressure is dropping too much.

**If you continue to feel unwell, talk to your doctor.**

#### *Things you must not do*

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

**Do not take NEBILET to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

#### *Things to be careful of*

**Be careful driving or operating machinery until you know how NEBILET affects you.**

This medicine may cause dizziness, light-headedness, or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

**Be careful when drinking alcohol while you are taking this medicine.**

If you drink alcohol, symptoms as dizziness or light-headedness may be worse.

**Be careful getting up from a lying or sitting position.**

You may feel dizzy or light-headed if you get up too quickly. Getting up slowly may help.

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#### **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NEBILET.**

**If you get any side effects, do not stop taking NEBILET® without first talking to your doctor.**

This medicine helps most people it is prescribed for, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**If you experience severe light-headedness, dizziness or fainting you must go to the Emergency department of your local hospital at once.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- headache, tiredness
- nausea or vomiting stomach upset, wind, diarrhoea or constipation
- disturbed sleep or nightmares
- coldness or numbness in the hands or feet

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

**Tell your doctor as soon as possible if you notice any of the following:**

- slow heart beat

- dizziness or fainting
- tingling or "pins and needles"
- abnormal thinking, depression or hallucinations
- sexual problems
- skin rashes and itching
- dry eyes or problems with eye sight
- an increase in a cramp-like pain in one or both legs that develops on walking.

The above list includes serious side effects that may require medical attention.

**If any of the following happen, tell your doctor immediately or go to Emergency at your nearest hospital:**

- swelling of the face, lips, tongue or throat that may cause difficulty swallowing or breathing
- chest tightness, shortness of breath or difficulty breathing
- swelling of the feet and ankles
- chest pain or changes in heart rate

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

**Do not be alarmed by this list of side effects. You may not experience any of them.**

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## After using NEBILET

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### Storage

**Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the pack/they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 30°C.**

**Do not store NEBILET or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product description

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### What it looks like

NEBILET tablets are white to off-white, round and biconvex.

Each pack contains 28 tablets, as 2 blister packs each with 14 tablets.

Each starter pack contains either 4 or 7 tablets, as 1 blister pack each with 4 or 7 tablets\*.

There are 3 different strengths of NEBILET® tablets.

- The 1.25mg tablets have a score on one side. The score is for identification purposes only and not to divide the tablet into equal doses.
- The 5mg tablet is cross-scored.
- The 10mg tablet is embossed with the number "10" on one side.

## Ingredients

Each tablet contains either 1.25mg, 5mg or 10mg of nebivolol (as nebivolol hydrochloride).

Each tablet also contains the following inactive ingredients:

- lactose
- maize starch
- croscarmellose sodium
- hypromellose
- polysorbate
- microcrystalline cellulose
- colloidal silica
- magnesium stearate.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

## Distributor

NEBILET is distributed in Australia by:

**A.Menarini Australia Pty Ltd**

Level 8, 67 Albert Ave,  
Chatswood NSW 2067

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## Australian Registration Numbers:

NEBILET® 1.25mg AUST R 148873.

NEBILET® 5mg AUST R 148874.

NEBILET® 10mg AUST R 148875.

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\* Not all presentations may be available.