

# NEBILET®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I taking NEBILET?

NEBILET contains the active ingredient nebivolol hydrochloride. NEBILET is used to treat high blood pressure (essential hypertension) or chronic heart failure. It is usually used in combination with other medicines. For more information, see Section [1. Why am I taking NEBILET?](#) in the full CMI.

### 2. What should I know before I take NEBILET?

Do not take NEBILET if you have ever had an allergic reaction to NEBILET or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I take NEBILET?](#) in the full CMI.

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### 3. What if I am taking other medicines?

Some medicines may interfere with NEBILET and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take NEBILET?

- Follow all directions given to you by your doctor. They will determine your dose. Take your medicine at about the same time each day. Swallow the tablets whole with a full glass of water. Do not crush or chew the tablets. 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.

More instructions can be found in Section [4. How do I take NEBILET?](#) in the full CMI.

### 5. What should I know while taking NEBILET?

#### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking NEBILET
- Keep all of your doctor's appointments so that your progress can be checked

	<ul style="list-style-type: none"> <li>● Tell your doctor if you believe that NEBILET is not helping your condition</li> <li>● If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not stop taking this medicine suddenly or lower the dosage without checking with your doctor</li> <li>● Do not take NEBILET to treat any other complaints unless your doctor tells you to</li> <li>● Do not give your medicine to anyone else, even if they have the same condition as you</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Be careful driving or operating machinery until you know how NEBILET affects you as this medicine may cause dizziness, light-headedness, or</li> </ul>

	drowsiness in some people.
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Tell your doctor if you drink alcohol</li> <li>• If you drink alcohol, symptoms such as dizziness or light-headedness may be worse</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep your tablets in the pack until it is time to take them</li> <li>• Keep your tablets in a cool dry place where the temperature stays below 25°C for NEBILET 1.25 mg tablet and below 30°C for NEBILET 5 mg and 10 mg tablets</li> </ul>

For more information, see Section [5. What should I know while taking NEBILET?](#) in the full CMI.

## **6. Are there any side effects?**

The most common side effects of NEBILET are headache, tiredness, nausea or vomiting, stomach upset, wind, diarrhoea, constipation, and coldness or numbness in the hands or feet. Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you experience 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; or chest pain or changes in heart rate.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# NEBILET®

**Active ingredient(s):** *nebivolol hydrochloride*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking NEBILET. Keep this leaflet with the medicines. You may need to read it again.

**You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NEBILET.**

**Where to find information in this leaflet:**

- [1. Why am I taking NEBILET?](#)
- [2. What should I know before I take NEBILET?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take NEBILET?](#)
- [5. What should I know while taking NEBILET?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking NEBILET?

**NEBILET contains the active ingredient nebivolol hydrochloride.** NEBILET belongs to a group of medicines called beta-blockers.

**NEBILET is used to treat high blood pressure (essential hypertension) or chronic heart failure.** It is usually used in combination with other medicines.

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.

### **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, in addition to other medicines. 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 hospitalised and/or dying from your heart condition.

## 2. What should I know before I take NEBILET?

### Warnings

#### Do not take NEBILET if:

- you are allergic to nebivolol hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine
- you have liver problems
- you have acute heart failure or cardiogenic shock, a serious heart condition causing low blood pressure
- you have a history of slow heart rate or uneven heart beating
- you have certain other heart conditions
- you have asthma, bronchitis or other lung disease with tightening of the airways
- you have untreated phaeochromocytoma, a rare tumour of the adrenal gland
- you have metabolic acidosis, where there is too much acid in the blood
- you have hypotension, low blood pressure
- you have a severe blood vessel disorder causing poor circulation in the arms and legs.

#### Check with your doctor if you:

- have any other medical conditions, such as:



- low blood pressure or poor circulation
- a slow heartbeat, 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
- or if you take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

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

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

Check with your doctor if you are pregnant or intend to become pregnant.

**Do not breastfeed 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

**Children under the age of 18 years**

**Do not give NEBILET to a child under the age of 18 years.**

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

**3. What if I am taking other medicines?**

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

**Some medicines may interfere with NEBILET and affect how it works.**

- those used to treat irregular or abnormal heartbeat (e.g. quinidine, flecainide, disopyramide, lignocaine, mexiletine, amiodarone)
- those used to treat high blood pressure (e.g. clonidine, guanfacine, moxonidine, methyldopa, amlodipine,

felodipine, nifedipine, nicardipine, nimodipine, reserpine, guanethidine)

- calcium channel blockers for high blood pressure or heart problems (e.g. verapamil, diltiazem)
- insulin and tablets used to treat diabetes
- those used to treat depression and anxiety (e.g. paroxetine, fluoxetine, phenothiazine, thioridazine, sedatives, antipsychotics)
- those used to treat excessive stomach acid (e.g. cimetidine). You should take NEBILET during a meal, and the antacid between meals.
- digoxin, a medicine used to treat heart failure
- other beta-blocker medicines (including beta-blocker eye drops) used to treat asthma, blocked nose or certain eye disorders such as glaucoma or dilation of the pupil
- anaesthetics
- baclofen, an antispasmodic drug
- amifostine, a protective medicine used during cancer treatment.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NEBILET.**

## **4. How do I take NEBILET?**

### **How much to take**

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

For the treatment of high blood pressure, the usual starting dose is one 5 mg tablet once daily. 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 1.25 mg tablet once daily. 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 10 mg once daily.

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.

- Follow the instructions provided and take NEBILET until your doctor tells you to stop.

## **When to take NEBILET**

- **NEBILET should be taken 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 NEBILET 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 to take NEBILET**

- Swallow the tablets whole with a full glass of water.
- Do not crush or chew the tablets.

## **If you forget to take NEBILET**

NEBILET should be taken regularly at the same time each day. If you miss your dose at the usual time, follow the instructions below.

**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 NEBILET as you would normally.**

Repeated skipping of doses should be avoided.

**Do not take a double dose to make up for the dose 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 NEBILET**

If you think that you have taken too much NEBILET, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (by calling **13 11 26** in Australia, or **0800 764 766** in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

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.

## **5. What should I know while taking NEBILET?**

### **Things you should do**

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

Remind any doctor, dentist or pharmacist you visit that you are taking NEBILET.

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

NEBILET may affect other medicines used during surgery. Your surgeon and anaesthetist should know well ahead of the date of your surgery so they can allow for your condition and medications.

**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 heartbeat. 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.**

**Call your doctor straight away if you:**

- If you become pregnant while taking this medicine.

**Things you should not do**

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



- 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. Continue taking NEBILET for as long as your doctor tells you.
- 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.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how NEBILET affects you.**

NEBILET 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.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Alcohol may worsen symptoms such as dizziness or light-headedness.

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.

## **Looking after your medicine**

**Keep your tablets in a cool dry place where the temperature stays below 25°C for NEBILET 1.25 mg tablet and below 30°C for NEBILET 5 mg and 10 mg tablets.**

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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

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

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

## **Getting rid of any unwanted medicine**

Do not take this medicine after the expiry date or if the packaging is torn or shows signs of tampering or the tablets do not look quite right.

If the medicine has expired or is damaged, or if your doctor tells you to stop taking this medicine, take it to any pharmacy for safe disposal.

## 6. Are there any side effects?

All medicines can have side effects.

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

If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>General body-related:</b></p> <ul style="list-style-type: none"><li>● headache, tiredness</li><li>● coldness or numbness in the hands or feet</li><li>● changes to the colour of fingers and toes in response to cold or stress</li><li>● feeling of light-headedness or dizziness</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<p>when getting out of bed or standing up</p> <p><b>Stomach and bowel-related:</b></p> <ul style="list-style-type: none"> <li>● nausea</li> <li>● vomiting</li> <li>● stomach upset</li> <li>● wind</li> <li>● diarrhoea</li> <li>● constipation</li> </ul> <p><b>Mind-related:</b></p> <ul style="list-style-type: none"> <li>● disturbed sleep or nightmares</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Allergic reaction-related:</b></p> <ul style="list-style-type: none"> <li>● swelling of the face, lips, tongue or throat that may cause difficulty swallowing or breathing</li> <li>● rashes, itching or hives on the skin</li> </ul> <p><b>General body-related:</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● chest tightness, shortness of breath or difficulty breathing</li> <li>● low blood pressure</li> <li>● swelling of the hands, feet or ankles</li> <li>● severe light-headedness, dizziness or fainting</li> <li>● tingling or "pins and needles"</li> </ul> <p><b>Heart-related:</b></p> <ul style="list-style-type: none"> <li>● slow heartbeat</li> <li>● chest pain</li> <li>● changes in heart rate</li> </ul> <p><b>Mind-related:</b></p> <ul style="list-style-type: none"> <li>● abnormal thinking, depression or hallucinations</li> </ul> <p><b>Sex-related:</b></p> <ul style="list-style-type: none"> <li>● impotence</li> </ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>● skin rashes and itching</li> <li>● worsening of psoriasis</li> </ul> <p><b>Eye-related:</b></p> <ul style="list-style-type: none"> <li>● dry eyes</li> </ul>	

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• problems with eye sight</li> </ul> <p><b>Muscle-related:</b></p> <ul style="list-style-type: none"> <li>• an increase in a cramp-like pain in one or both legs that develops on walking</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

This medicine is not addictive.

## What NEBILET contains

<b>Active ingredient (main ingredient)</b>	Each tablet contains 1.25 mg, 5 mg or 10 mg of nebivolol (as nebivolol hydrochloride).
<b>Other ingredients (inactive ingredients)</b>	Each tablet also contains the following inactive ingredients: <ul style="list-style-type: none"><li>• lactose monohydrate</li><li>• maize starch</li><li>• croscarmellose sodium</li><li>• hypromellose</li><li>• polysorbate 80</li><li>• microcrystalline cellulose</li><li>• colloidal anhydrous silica</li><li>• magnesium stearate</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NEBILET

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

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

## **What NEBILET looks like**

NEBILET tablets are almost white, round and biconvex.

NEBILET 1.25 mg tablet has a score on one side. The score is for identification purposes only and not to divide the tablet into equal doses (AUST R 148873).

NEBILET 5 mg tablet is cross-scored (AUST R 148874).

NEBILET 10 mg tablet is embossed with the number "10" on one side (AUST R 148875).

NEBILET 1.25 mg/5 mg composite starter titration pack contains 42 tablets of 1.25 mg and 14 tablets of 5 mg (AUST R 148895).

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.

Not all pack sizes may be marketed.

## **Who distributes NEBILET**

A. Menarini Australia Pty Ltd

Level 8, 67 Albert Ave, Chatswood NSW 2067

Medical Information: 1800 644 542



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This leaflet was prepared in April 2023.

For the most up to date version of this leaflet, please go to [www.menarini.com.au/cmi](http://www.menarini.com.au/cmi)

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