

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.

1. Why am I using Nepiten?

Nepiten contains the active ingredient Nebivolol hydrochloride. Nepiten 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 using Nepiten?](#) in the full CMI.

2. What should I know before I use Nepiten?

Do not use if you have ever had an allergic reaction to [medicine] 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 use Nepiten?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Nepiten 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 use Nepiten?

- 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 use Nepiten?](#) in the full CMI.

5. What should I know while using Nepiten?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are taking Nepiten - Keep all of your doctor's appointments so that your progress can be checked - Tell your doctor if you believe that Nepiten is not helping your condition - If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly
Things you should not do	- Do not stop taking this medicine suddenly or lower the dosage without checking with your doctor - Do not take Nepiten 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 driving or operating machinery until you know how Nepiten affects you as this medicine may cause dizziness, light-headedness, or drowsiness in some people.
Drinking alcohol	- Tell your doctor if you drink alcohol - If you drink alcohol, symptoms such as dizziness or light-headedness may be worse
Looking after your medicine	- Keep your tablets in the pack until it is time to take them - Keep your tablets in a cool dry place where the temperature stays below 25°C

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

6. Are there any side effects?

The most common side effects of Nepiten 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.

Nepiten®

Active ingredient(s): Nebivolol hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Nepiten. **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 Nepiten.**

Where to find information in this leaflet:

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

1. Why am I using Nepiten?

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

Nepiten 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):

Nepiten 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:

Nepiten 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 use Nepiten?

Warnings

Do not use Nepiten 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 Nepiten 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 Nepiten 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 Nepiten 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 Nepiten 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 Nepiten.

4. How do I use Nepiten?

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 Nepiten.

• Chronic Heart Failure:

For the treatment of chronic heart failure, your doctor will start you on a low dose of Nepiten, 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 Nepiten 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 use Nepiten until your doctor tells you to stop.

When to take Nepiten

- **Nepiten 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 Nepiten 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 Nepiten.

How to take Nepiten

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

If you forget to take Nepiten

Nepiten should be used 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 Nepiten 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 use too much Nepiten

If you think that you have used too much Nepiten, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia**); 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 using Nepiten?

Things you should do

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

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

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

Nepiten 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 Nepiten.

This medicine may affect the results of some tests.

Tell your doctor if you believe that Nepiten 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.

Nepiten 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. Nepiten 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 Nepiten. 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 Nepiten, 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 Nepiten 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 Nepiten 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 Nepiten affects you.

Nepiten 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 lightheadedness.

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.

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
General body-related: - headache, tiredness - coldness or numbness in the hands or feet - changes to the colour of fingers and toes in response to cold or stress - feeling of light-headedness or dizziness when getting out of bed or standing up Stomach and bowel-related: - nausea - vomiting - stomach upset - wind - diarrhoea - constipation Mind-related: - disturbed sleep or nightmares	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic reaction-related: - swelling of the face, lips, tongue or throat that may cause difficulty swallowing or breathing - rashes, itching or hives on the skin General body-related:	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of

Serious side effects	What to do
- chest tightness, shortness of breath or difficulty breathing - low blood pressure - swelling of the hands, feet or ankles - severe light-headedness, dizziness or fainting - tingling or "pins and needles" Heart-related: - slow heartbeat - chest pain - changes in heart rate Mind-related: - abnormal thinking, depression or hallucinations Sex-related: - impotence Skin-related: - skin rashes and itching - worsening of psoriasis Eye-related: - dry eyes - problems with eye sight Muscle-related: - an increase in a cramp-like pain in one or both legs that develops on walking	these serious side effects.

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. 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.

What Nepiten contains

Active ingredient (main ingredient)	Nebivolol (as Nebivolol hydrochloride).
Other ingredients	Lactose monohydrate Maize starch,

(inactive ingredients)	Croscarmellose sodium, Hypromellose, Polysorbate 80, Microcrystalline cellulose, Silicon dioxide Magnesium stearate
Potential allergens	Lactose monohydrate

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

What Nepiten looks like

Nepiten 1.25mg: White to off white, circular flat face bevelled edge uncoated tablets debossed with 'U 53' on one side and plain on the other side. AUST R 311682.

Nepiten 5mg: White to off white, circular, biconvex uncoated tablets debossed with "T 56" on one side and cross score line on the other side. AUST R 311693.

Nepiten 10 mg: White to off white, circular, biconvex uncoated tablets debossed with "T 57" on one side and score line on the other side. AUST R 311695.

Who distributes Nepiten

SPONSOR

Southern Cross Pharma Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, VIC, 3128

Email: ghinfo@generichealth.com.au

Phone: +61 3 9809 7900

Website: www.generichealth.com

Distributor

Alphapharm Pty Ltd trading as Viatris

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