

NEBIVOLOL SANDOZ

nebivolol hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NEBIVOLOL SANDOZ.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NEBIVOLOL SANDOZ 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 NEBIVOLOL SANDOZ is used for

NEBIVOLOL SANDOZ 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):

NEBIVOLOL SANDOZ 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:

NEBIVOLOL SANDOZ 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 NEBIVOLOL SANDOZ

When you must not take it

Do not take NEBIVOLOL SANDOZ if you have an allergy to:

- any medicine containing nebivolol 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 NEBIVOLOL SANDOZ 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 breastfeed if you are taking this medicine.

The active ingredient in NEBIVOLOL SANDOZ passes into breast milk and there is a

possibility that your baby may be affected.

Do not give NEBIVOLOL SANDOZ 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 NEBIVOLOL SANDOZ 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 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
- pheochromocytoma, a rare tumour of the adrenal gland
- a lactose intolerance

Tell your doctor if you are pregnant or intend 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 NEBIVOLOL SANDOZ.

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 NEBIVOLOL SANDOZ may interfere with each other. These include:

- 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)
- 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. phenelzine, tranylcypromine, paroxetine, sertraline, sedatives, phenothiazine)
- those used to treat excessive stomach acid (e.g. cimetidine)
You should take NEBIVOLOL SANDOZ 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
- baclofen (an antispasmodic drug)
- amifostine (a protective medicine used during cancer treatment)

These medicines may be affected by NEBIVOLOL SANDOZ 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 NEBIVOLOL SANDOZ

You should only start taking NEBIVOLOL SANDOZ 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 NEBIVOLOL SANDOZ without speaking to your doctor first.

You should not stop treatment with NEBIVOLOL SANDOZ 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 NEBIVOLOL SANDOZ.

Chronic Heart Failure:

For the treatment of chronic heart failure, your doctor will start you on a low dose of NEBIVOLOL SANDOZ, 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 NEBIVOLOL SANDOZ 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 NEBIVOLOL SANDOZ.

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 on 13 11 26 (Australia) or 0800 764 766 (New Zealand) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much NEBIVOLOL SANDOZ.

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.

While you are using NEBIVOLOL SANDOZ

Things you must do

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

are taking NEBIVOLOL SANDOZ.

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 NEBIVOLOL SANDOZ.

This medicine may affect the results of some tests.

Tell your doctor if you believe that NEBIVOLOL SANDOZ 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.

NEBIVOLOL SANDOZ 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. NEBIVOLOL SANDOZ 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 NEBIVOLOL SANDOZ. 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 NEBIVOLOL SANDOZ, 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 NEBIVOLOL SANDOZ 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 NEBIVOLOL SANDOZ 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.

Side effects

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

If you get any side effects, do not stop taking NEBIVOLOL SANDOZ 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 some unwanted side effects. Sometimes they are serious, but 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 lightheadedness, dizziness or fainting, you must go to Accident and Emergency at the nearest 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 heartbeat
- 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 rare but serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and 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 rare but very serious side effects. You may need urgent medical attention or hospitalisation.

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

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.

After using NEBIVOLOL SANDOZ

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 NEBIVOLOL SANDOZ 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.

Product description

What it looks like

NEBIVOLOL SANDOZ tablets are almost white, round and biconvex.

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

There are 3 different strengths of NEBIVOLOL SANDOZ tablets.

Nebivolol Tablets 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.

Nebivolol Tablets 5mg

White to off white, circular, biconvex uncoated tablets debossed with "T 56" on one side and cross score line on the other side.

Nebivolol Tablets 10 mg:

White to off white, circular, biconvex uncoated tablets debossed with "T 57" on one side and score line on the other side.

Ingredients

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

Each tablet also contains the following inactive ingredients:

- lactose monohydrate
- maize starch
- croscarmellose sodium
- hypromellose
- polysorbate 80
- microcrystalline cellulose
- colloidal anhydrous silica
- magnesium stearate

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

Supplier

NEBIVOLOL SANDOZ is supplied in Australia by:

Southern Cross Pharma Pty Ltd
Suite 5/118 Church St
HAWTHORN VIC 3122

Australian Registration Numbers:

NEBIVOLOL SANDOZ 1.25mg
AUST R 311723

NEBIVOLOL SANDOZ 5mg
AUST R 311724

NEBIVOLOL SANDOZ 10mg
AUST R 311725

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