Package leaflet: Information for the patient

Nebivolol Torrent 2.5 mg tablets
Nebivolol Torrent 10 mg tablets
nebivolol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nebivolol Torrent is and what it is used for
2. What you need to know before you take Nebivolol Torrent
3. How to take Nebivolol Torrent
4. Possible side effects
5. How to store Nebivolol Torrent
6. Contents of the pack and other information

1. What Nebivolol Torrent is and what it is used for

Nebivolol Torrent contain nebivolol, a cardiovascular drug belonging to the group of selective beta-blocking agents (i.e. with a selective action on the cardiovascular system). It prevents increased heart rate, controls heart pumping strength. It also exerts a dilating action on blood vessels, which contributes as well to lower blood pressure.
It is used to treat raised blood pressure (hypertension).
Nebivolol Torrent are also used to treat mild and moderate chronic heart failure in patients aged 70 or over, in addition to other therapies.

2. What you need to know before you take Nebivolol Torrent

Do not take Nebivolol Torrent
- if you are allergic to nebivolol or any of the other ingredients of this medicine (listed in section 6),
- if you have one or more of the following disorders:
  - low blood pressure
  - serious circulation problems in the arms or legs
  - very slow heartbeat (less than 60 beats per minute)
  - certain heart conduction disorders (2nd and 3rd degree heart block – AV block [without pacemaker])
  - sick sinus syndrome (a certain type of disturbance in heart rhythm) including sino-arterial block (SA block)
  - heart failure, which has just occurred or which has recently become worse, or you are receiving treatment for circulatory shock due to acute heart failure by intravenous drip feed to help your heart work
  - asthma or wheezing (now or in the past)

- untreated phaeochromocytoma, a tumour located on top of the kidneys (in the adrenal glands)
- liver function disorder
- a metabolic disorder (metabolic acidosis), for example, diabetic ketoacidosis.

Warnings and precautions
Talk to your doctor or pharmacist before taking Nebivolol Torrent.

Inform your doctor if you have or develop one of the following problems:
- abnormally slow heartbeat
- a type of chest pain due to spontaneously occurring heart cramp called Prinzmetal angina
- untreated chronic heart failure
- 1st degree heart block (a kind of light heart conduction disorder that affects heart rhythm)
- poor circulation in the arms or legs, e.g. Raynaud's disease or syndrome, cramp-like pains when walking
- prolonged breathing problems
- diabetes: this medicine has no effect on blood sugar, but it could conceal the warning signs of a low sugar level (e.g. palpitations, fast heartbeat) and could increase the risk of severe hypoglycaemia when used with certain type of antidiabetic drugs called sulfonylureas (e.g. gliquidone, gliclazide, glibenclamide, glipizide, glimepiride or tolbutamide)
- overactive thyroid gland: this medicine may mask the signs of an abnormally fast heart rate due to this condition
- allergy: this medicine may intensify your reaction to pollen or other substances you are allergic to
- psoriasis (a skin disease - scaly pink patches) or if you have ever had psoriasis
- if you have to have surgery, always inform your anaesthetist that you are on Nebivolol Torrent before being anaesthetised.

If you have serious kidney problems do not take Nebivolol for heart failure and tell your doctor.

You will be regularly monitored at the beginning of your treatment for chronic heart failure by an experienced physician (see section 3). This treatment should not be stopped abruptly unless clearly indicated and evaluated by your doctor (see section 3).

Children and adolescents
Because of the lack of data on the use of the product in children and adolescents, Nebivolol Torrent are not recommended for use in them.

Other medicines and Nebivolol Torrent
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Always tell your doctor or pharmacist if you are using or receiving any of the following medicines in addition to Nebivolol Torrent:
- medicines for diabetes such as insulin or oral antidiabetics drugs
- Medicines for controlling the blood pressure or medicines for heart problems (such as amiodarone, amlodipine, cibenzoline, clonidine, digoxin, diltiazem, disopyramide, felodipine, -flecainide, guanfacin, hydroquinidine, lacidipine, lidocaine, methyldopa, mexiletine, moxonidine, nicardipine, nifedipine, nimodipine, nitrendipine, propafenone, quinidine, rilmenidine, verapamil).
- Sedatives and therapies for psychosis (a mental illness) e.g. barbiturates (also used for epilepsy), phenothiazine (also used for vomiting and nausea), levomepromazin, and thioridazine.
- Medicines for depression e.g. amitriptyline, paroxetine, fluoxetine, bupropion.
- Medicines used for anaesthesia during an operation.
- Medicines for asthma, blocked nose or certain eye disorders such as glaucoma (increased pressure in the eye) or dilation (widening) of the pupil.

- Baclofen (an antispasmodic drug); Amifostine (a protective medicine used during cancer treatment).
- Chloroquine (medicine used to treat malaria).
- Terbinafne (a medicine used to treat fungal infections).

All these medicines as well as nebivolol may influence the blood pressure and/or heart function.

- Medicines for treating excessive stomach acid or ulcers (antacid drug), e.g. cimetidine: you should take Nebivolol Torrent during a meal and the antacid medicine between meals.

Nebivolol Torrent with food and drink
Please refer to section 3.

Pregnancy and breast-feeding
Beta-blockers, including nebivolol, can affect pregnancy and may harm the unborn baby. They can reduce blood flow to the placenta, which may lead to slower growth, miscarriage, premature birth or death of the foetus during pregnancy. Nebivolol Torrent should not be used during pregnancy, unless clearly necessary.
If nebivolol is required during pregnancy, close monitoring is required. After birth, your baby needs to be monitored for signs of low blood sugar (hypoglycaemia) and slow heart rate (bradycardia), which can occur within the first three days of life.
Mothers receiving Nebivolol Torrent should not breastfeed.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
This medicine may cause dizziness or fatigue. If affected, do not drive or operate machinery.

Nebivolol Torrent contains lactose
This product contains lactose. Patients with rare hereditary problems of galactose intolerance, the total lactase deficiency or glucose-galactose malapsorption should not take this medicinal product.

Nebivolol Torrent contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Nebivolol Torrent

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

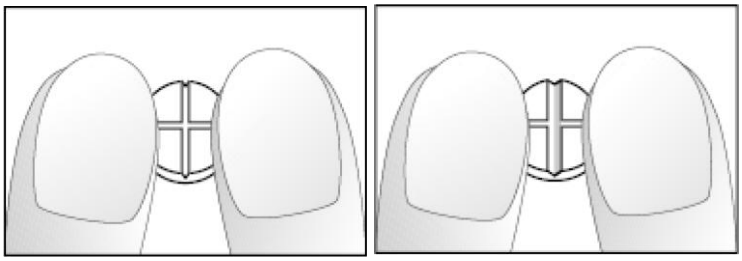
Nebivolol Torrent may be taken before, during or after the meal, but, alternatively, you can take it independently of meals. The tablet is best taken with some water.

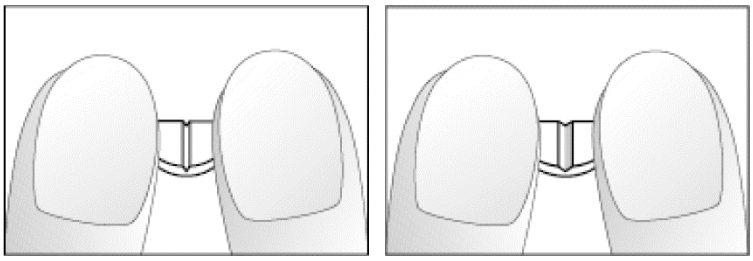
Nebivolol Torrent 10 mg tablets: The tablet can be divided into equal doses.

Treatment of raised blood pressure (hypertension)
- The recommended dose is 5 mg of nebivolol once a day. The dose should be taken preferably at the same time of the day.
- Older patients and patients with a kidney disorder will usually start with 2.5 mg of nebivolol daily.
- The therapeutic effect on blood pressure becomes evident after 1-2 weeks of treatment. Occasionally, the optimal effect is reached only after 4 weeks.

Treatment of chronic heart failure
- Your treatment will be started and closely supervised by an experienced physician.
- Your doctor will start your treatment with 1.25 mg per day. This may be increased after 1-2 weeks to 2.5 mg per day, then to 5 mg per day and then to 10 mg per day until the correct dose is reached for you. Your doctor will prescribe the dose that is right for you at each step and you should closely follow his/her instructions.
- The maximum recommended dose is 10 mg a day.
- You will need to be under the close supervision for 2 hours by an experienced physician when you start treatment and every time your dose is increased.
- Your doctor may reduce your dose if necessary.
- You should not stop treatment abruptly as this can make your heart failure worse.
- Patients with serious kidney problems should not take this medicine.
- Take your medicine once daily, preferably at about the same time of day.

If you have been told by your doctor to take ¼ (quarter) or ½ (half) tablet of Nebivolol Torrent 10mg daily, please refer to the instructions below on how to break Nebivolol Torrent 10 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 10 mg cross-scored tablet in half.


Diagrams 3 and 4: Easy breaking of half of the Nebivolol 10 mg cross-scored tablet into quarters.

- Your doctor may decide to combine Nebivolol Torrent with other medicines to treat your condition.
- Do not use in children or adolescents.

If you take more Nebivolol Torrent than you should
If you accidentally take an overdose of this medicine, tell your doctor or pharmacist immediately. The most frequent symptoms and signs of a Nebivolol Tablet overdose are very slow heart beat (bradycardia), low blood pressure with possible fainting (hypotension), breathlessness such as in asthma (bronchospasm), and acute heart failure. You can take activated charcoal (which is available at your pharmacy) while you wait for the arrival of the doctor.

If you forget to take Nebivolol Torrent
If you forget a dose of Nebivolol Torrent, but remember a little later on that you should have taken it, take that day's dose as usual. However, if a long delay has occurred (e.g. several hours), so that the next due dose is near, skip the forgotten dose and take the next, scheduled, normal dose at the usual

time. Do not take a double dose to make up for a forgotten dose. Repeated skipping, however, should be avoided.

If you stop taking Nebivolol Torrent
You should always consult with your doctor before stopping Nebivolol Tablet treatment, whether you are taking it for high blood pressure or chronic heart failure. You should not stop Nebivolol treatment abruptly as this can temporarily make your heart failure worse. If it is necessary to stop Nebivolol treatment for chronic heart failure, the daily dose should be decreased gradually, by halving the dose, at weekly intervals.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Nebivolol Torrent and seek medical help immediately if you have any of the following reactions:
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in breathing and swallowing (angioedema), severe itching of the skin (with raised lumps). Frequency not known (cannot be estimated from the available data).

When Nebivolol Torrent is used for the treatment of raised blood pressure, the possible side effects are:

Common side effects (may affect up to 1 in 10 people)
- Headache, dizziness, tingling skin, shortness of breath, constipation, nausea, diarrhoea, tiredness, swollen hands or feet.

Uncommon side effects (may affect up to 1 in 100 people)
- Nightmares, depression, abnormal vision, unusually low heart rate (slow pulse), weak heart performance, conduction defects in the heart, low blood pressure, cramp-like leg pains on walking, wheezing or shortness of breath (bronchospasm), indigestion, flatulence, vomiting, skin rash, itchiness, impotence.

Very rare side effects (may affect up to 1 in 10,000 people)
- Fainting (syncope), worsening of psoriasis (a skin disease – scaly pink patches).

Not known (frequency cannot be estimated from the available data)
- Allergy (hypersensitivity), itchy skin rash (hives).

The following side effects have also been reported with similar medicines: hallucinations, psychotic reactions (psychoses), confusion, cold/bluish-red discoloration of the arms and legs, pain in fingers and toes which first turn bluish, then whitish, and finally reddish (Raynaud's syndrome), dry eyes and also formation of new connective tissue in the eyes and the diaphragm (practolol-type oculo mucocutaneous toxicity).

When Nebivolol Torrent are used for the treatment of chronic heart failure, the possible side effects are:

Very common side effects (may affect more than 1 in 10 people)
- Dizziness, slow heartbeat.

Common side effects (may affect up to 1 in 10 people)
- Worsening of heart failure, low blood pressure (such as feeling faint when getting up quickly), inability to tolerate this medicine, heart conduction disorder that affects heart rhythm (1st degree AV-block), swelling of the lower limbs (such as swollen ankles).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nebivolol Torrent

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister foil after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nebivolol Torrent contains
- The active substance is nebivolol.
  Each tablet contains 2.5 mg of nebivolol equivalent to 2.725 mg of nebivolol hydrochloride.
  Each tablet contains 10 mg of nebivolol equivalent to 10.900 mg of nebivolol hydrochloride.

- The other ingredients are: Lactose monohydrate, Maize Starch, Croscarmellose Sodium, Hypromellose 2910 (6 cps), Silica, colloidal anhydrous, Cellulose, Microcrystalline, Lake of Indigo carmine (E132), Magnesium Stearate

What Nebivolol Torrent looks like and contents of the pack

Nebivolol Torrent 2.5 mg tablets: Light Blue coloured with dark blue spots, round, uncoated tablets, plain on both sides having approximate diameter of 5 mm.

Nebivolol Torrent 10 mg tablets: Light Blue coloured with dark blue spots, round, biconvex, uncoated tablets with cross break line on one side and plain on other side having approximate diameter of 9 mm.

Nebivolol Torrent 2.5 mg tablets are available in OPA/Al/PVC//Al blister placed into cardboard boxes containing 7, 14, 28, 30, 50 and 100 tablets.

Nebivolol Torrent 10 mg tablets are available in OPA/Al/PVC//Al blister placed into cardboard boxes containing 7, 14, 28, 30, 50 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Torrent Pharma (Malta) Ltd.
HHF 028 Hal Far Industrial Estate
Birzebbuga BBG 3000

Malta.

Manufacturer

Heumann Pharma GmbH & Co. Generica KG
Suedwestpark 50,
Gebersdorf
Nuremberg, Bavaria 90449,
Germany

Torrent Pharma (Malta) Ltd.
HHF 028 Hal Far Industrial Estate
Birzebbuga BBG 3000
Malta

This medicine is authorised in the Member States of the European Economic Area under the following names:

Malta:	Nebivolol Torrent 2.5 mg tablets Nebivolol Torrent 10 mg tablets
Germany:	Nebivolol Heumann 2,5 mg tabletten Nebivolol Heumann 10 mg tabletten

This leaflet was last revised in Sep 2026.