

Package leaflet: Information for the patient
Nortenolol 25mg, 50mg and 100mg Film-Coated Tablets
(Atenolol)

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

1. What Nortenolol is and what it is used for

The active ingredient in Nortenolol is **Atenolol** which belongs to a group of medicines called beta-blockers, which help slow the heartbeat and relax the blood vessels. This reduces blood pressure and the heart's demand for oxygen.

Nortenolol is used to treat the following conditions:

- **High blood pressure** (hypertension)
- **Chest pain** (angina pectoris): Nortenolol helps to prevent or reduce chest pains which may occur when your heart cannot get enough oxygen, such as when doing exercise
- **Irregular heartbeat** (cardiac dysrhythmias): Nortenolol helps to control abnormal heart beats, by slowing the heart rate
- **Protect the heart in the early treatment after a heart attack** (myocardial infarction): Nortenolol helps to reduce the damage to the heart if taken shortly after a heart attack and decrease the risk of continued illness

2. What you need to know before you take Nortenolol

Do not take Nortenolol if:

- You are allergic (hypersensitive) to Atenolol, other beta-blockers or any of the other ingredients of this medicine (listed in section 6)
- You have heart problems such as:
 - 2nd or 3rd degree heart block
 - Weakened heart (cardiogenic shock)
 - **Uncontrolled** heart failure
 - Irregular heartbeat (sick sinus syndrome) or a slow heart rate [bradycardia] (less than 45 beats per minute)
- You have low blood pressure (hypotension)
- You have very poor circulation
- You have phaeochromocytoma (a tumour near your kidney which can cause high blood pressure) which is untreated
- You have increased acidity of the blood (metabolic acidosis)

Warnings and precautions

Talk to your doctor before taking this medicine:

- **If you have ever had wheezing or asthma or other breathing problems**
- If you suffer from heart conditions such as **controlled** heart failure, a slow heart rate (50–55 beats per minute) or 1st degree heart block
- If you have a type of chest pain (angina) called Prinzmetal’s angina
- If you are diabetic as Nortenolol may hide the symptoms of having low blood sugar levels
- If you have thyrotoxicosis (a condition caused by an overactive thyroid gland). Nortenolol may hide the symptoms of thyrotoxicosis
- If you have liver or kidney problems. You may require a lower dose than stated
- If you have circulatory problems, as Nortenolol may make this condition worse
- If you have allergies, as beta-blockers may increase the allergies and the seriousness of the allergic reaction. If you take adrenaline (epinephrine) for allergic reactions, you may not respond to your normal dose
- If you have psoriasis (a skin condition), as the condition may be aggravated by Nortenolol
- If you are due to have surgery as treatment with Nortenolol should be discontinued for at least 24-hours prior to the procedure (see “Other medicines and Nortenolol” section)

Other medicines and Nortenolol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those bought without a prescription. This includes herbal medicines.

Nortenolol **may** interact with the following medicines:

- Water tablets (diuretics), guanethidine, reserpine or other medicines used to treat high blood pressure (including vasodilators)
- Medicines for regulating the heartbeat such as disopyramide, quinidine and amiodarone
- Insulin and oral antidiabetic medicines to treat diabetes, such as metformin
- Cimetidine, for stomach ulcers and indigestion
- Hydralazine, for high blood pressure
- Verapamil and diltiazem, used to treat high blood pressure and chest pains (angina)
- Medicines for heart failure, such as digoxin (digitalis glycosides)
- Medicines for depression, such as moclobemide (MAO inhibitors)
- Amphetamines, medicines for tiredness
- Medicines which stimulate the heart, such as ephedrine, adrenaline and noradrenaline (sympathomimetic amines)
- Medicines to relieve pain and inflammation, such as ibuprofen and indometacin (Non-Steroidal Anti-Inflammatory Drugs – NSAIDs)
- Lidocaine, used to relieve pain or numb an area of the skin before surgery
- Procainamide, used for an irregular heartbeat
- Medicines for depression such as amitriptyline (tricyclic antidepressants), sleeping difficulties such as amobarbital (barbiturates), feeling sick (nausea), pain relief or mental problems such as chlorpromazine (phenothiazines)
- Calcium or aluminium hydroxide, for indigestion

Stopping taking other high blood pressure medicines:

If stopping treatment with clonidine, calcium channel blocking agents (such as nifedipine), diazoxide, reserpine or other medicines which may lower your blood pressure, care should be taken.

Beta-blockers may increase the withdrawal effect and make your blood pressure worse.

If clonidine and Nortenolol are used together, your doctor will advise you to stop taking Nortenolol several days before stopping clonidine. If Nortenolol is going to be used instead of clonidine, your doctor will advise you to begin taking Nortenolol several days after clonidine has been stopped.

Surgery

Nortenolol may react with certain anaesthetics, so if you are due to have surgery you should tell the anaesthetist that you are taking Nortenolol Tablets.

If you are told to stop taking Nortenolol Tablets this must be at least 24 hours before surgery (see “Warnings and precautions” section).

Taking this medicine with alcohol

If alcohol is taken together with Nortenolol, your blood levels of beta- blockers may increase.

Pregnancy and breast-feeding

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

Pregnancy

You should not use this medicine unless told to do so by your doctor.

Breast-feeding

If you are breast-feeding you should not use this medicine unless told to do so by your doctor. A significant amount of the active ingredient atenolol passes in to the breast milk.

If you do take Nortenolol during pregnancy or whilst breast-feeding, your infant should be monitored for a slow heartbeat (bradycardia), breathing problems, low blood pressure (hypotension) and low blood sugar levels (hypoglycaemia).

Driving and using machines

Nortenolol is unlikely to affect your ability to drive, operate machinery or undertake tasks which require a high level of concentration. However, you may feel dizzy or tired whilst taking this medicine. If affected do not drive or operate machinery.

Nortenolol contains:

- Nortenolol 25mg, 50mg and 100mg Tablets contain **lactose**. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.
- Nortenolol 100mg Tablets contain the colouring agent **Sunset Yellow FCF** (E110), which may cause allergic reaction.

3. How to take Nortenolol

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

- These tablets are to be taken orally.

High blood pressure (hypertension):

- Normal dose is 100mg tablet daily. Some patients may respond better to one 50mg tablet daily.
- After 1 or 2 weeks of treatment, your high blood pressure should return to normal.
- If necessary your doctor may also prescribe you other antihypertensive medicines to reduce the blood pressure further.

Chest pain (angina pectoris):

Normal dose is one 100mg tablet once a day or one 50mg tablet twice a day.

Abnormal heart rhythm (cardiac dysrhythmias):

The initial step may be an injection of atenolol to control the rhythm of the heart. To maintain your heart rhythm, the normal dose is one 50mg tablet or one 100mg tablet daily given as a single dose.

Heart attack (myocardial infarction):

- Within 12 hours of chest pain and following an injection of atenolol, if there are no side effects, after 15 minutes you may be given a 50mg Nortenolol Tablet, followed by another 12 hours later. Another 12 hours after this, a 100mg tablet is given once daily.
- Your doctor will monitor you closely because if your heart rate lowers or you suffer from high blood pressure it may be necessary to stop treatment with Nortenolol.

Older people:

If you are older, your dose may need to be reduced, particularly if you suffer from kidney problems.

If you suffer from kidney failure:

Your doctor will advise you of the correct dose to take since atenolol (the active ingredient in Nortenolol) passes through the kidneys.

Use in children

Nortenolol is **not** recommended for use in children.

If you take more Nortenolol than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of overdose are: slower heartbeat (bradycardia), low blood pressure (hypotension), difficulty in breathing or wheezing (bronchospasm) and heart problems.

If you forget to take Nortenolol

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

If you stop taking Nortenolol

It is important that you keep taking this medicine for as long as your doctor has told you to.

When your doctor tells you to stop taking Nortenolol this should be done **gradually**, over 1 – 2 weeks and you should be monitored by your doctor.

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.

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness.
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)
- Skin rashes with the formation of wheals (urticaria)

Common (may affect up to 1 in 10 people)

- Slower heartbeat (bradycardia)
- Cold hands and feet
- Stomach problems
- Feeling tired (fatigue)

Uncommon (may affect up to 1 in 100 people)

- Disturbed sleep
- Increase in liver enzyme levels (detected through blood test)

Rare (may affect up to 1 in 1,000 people)

- Heart failure or heart block
- Fainting or dizziness when going from lying or sitting to standing up, due to a sudden drop in blood pressure (postural hypotension)
- Worsening of pain and/or cramping in the lower leg (usually calf) (intermittent claudication)
- Poor blood circulation which makes the toes and fingers numb and pale (Raynaud's phenomenon)
- Tingling or numbness in the hands or feet (paraesthesia)
- Dizziness
- Headache
- Mood changes
- Nightmares
- Feeling confused
- Changes in personality (psychoses), seeing or hearing things that are not real (hallucinations)
- Liver problems including cholestasis (build up of bile acids in the bloodstream causing persistent itch)
- Skin rash resulting from bleeding into the skin from small blood vessels (purpura)
- Reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- Hair loss (alopecia)
- Skin rashes and scaly skin patches (psoriasis) or worsening of the condition
- Dry mouth
- Dry eyes, other eye problems, such as blurred vision, sore eyes or conjunctivitis (infection that causes inflammation of the eye, red eyes, itchiness and discharge)
- Being unable to get an erection (impotence)
- Breathing problems in patients with asthma or a history of asthmatic problems (bronchospasm)

Very rare (may affect less than 1 in 10,000 people)

- Changes to some of the cells or other parts of your blood. Your doctor may take blood samples every so often to check whether Nortenolol has had any effect on your blood

Other side effects (frequency not known)

- Narrowing of the blood vessels (peripheral vasoconstriction)
- Disorders of the nervous system e.g. "creeping" sensation and other sensory disorders affecting hands &/or feet (peripheral neuritis)
- Feeling anxious and nervous
- Constipation (may also be a symptom of sclerosing peritonitis)
- Stomach pains (may also be a symptom of retroperitoneal fibrosis)
- Increase in liver enzyme levels and/or bilirubin (detected through blood test)
- Increase in certain type of white blood cells (eosinophilia). Symptoms include frequent wheezing and breathlessness, abdominal pain, diarrhoea, fever, cough & rashes (diagnosed through blood test)
- Reduction in white blood cells, which may make infections more likely (leucopenia & agranulocytosis)
- Itching (pruritis)
- Inflammation of the penis, which can develop in to a hardened scar (Peyronies' disease)
- Inflammation of the lungs which causes breathlessness, cough and raised temperature (pneumonitis)
- Condition that causes scarring of the lungs (pulmonary fibrosis)
- Inflammation of the lining surrounding the lungs (pleurisy)
- Lupus-like syndrome (a disease where the immune system produces antibodies that attacks mainly skin and joints)

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nortenolol

- Keep this medicine out of the sight and reach of children.
- Store in the original package in order to protect from light and moisture.
- Do not use this medicine after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Nortenolol Tablets contains:

- Nortenolol 25mg Tablet: each film-coated tablet contains atenolol 25mg
- Nortenolol 50mg Tablet: each film-coated tablet contains atenolol 50mg
- Nortenolol 100mg Tablet: each film-coated tablet contains atenolol 100mg

The other ingredients are: lactose, microcrystalline cellulose, talc, maize starch, povidone, sodium starch glycollate, sodium laurilsulfate, colloidal silicon dioxide, stearic acid, magnesium stearate, titanium dioxide (E171), dibutyl phthalate and hypromellose.

Nortenolol 100mg Tablets also contain the colouring agent Sunset Yellow (E110).

What Nortenolol Tablets look like and contents of the pack:

- Nortenolol 25mg Tablets: white, bi-convex, unscored, film-coated tablets marked "A25"
- Nortenolol 50mg Tablets: white/off-white, bi-convex, unscored, film-coated tablets marked "A50"
- Nortenolol 100mg Tablets: bright orange, unscored, film-coated tablets marked "A100"

Nortenolol Tablets are available in:

Nortenolol tablets are available in blister packs of 28 or 30 tablets and securitainers of 100 tablets.

Not all pack sizes or pack types may be marketed.

Marketing Authorisation Holder and Manufacturer:

Tillomed Laboratories Ltd.
3 Howard Road,
Eaton Socon, St. Neots,
Cambridgeshire, PE19 8ET,
UK

Product Licence Numbers:

- Nortenolol 25mg Film-coated Tablets – PA 644/3/1
- Nortenolol 50mg Film-coated Tablets – PA 644/3/2
- Nortenolol 100mg Film-coated Tablets – PA 644/3/3

This leaflet was last revised in July 2015

Till.Ver.8s