

The medicine is dispensed with
a doctor's prescription only

Normiten® 25 mg Tablets

Composition
Each tablet contains:
Atenolol 25 mg

Normiten® 50 mg Tablets

Composition
Each tablet contains:
Atenolol 50 mg

Normiten® 100 mg Tablets

Composition
Each tablet contains:
Atenolol 100 mg

For the list of inactive ingredients in the preparation, see section 6 – "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for use in children.

1. WHAT IS THE MEDICINE INTENDED FOR?

A preparation from the beta-adrenergic receptor blocker (beta-blockers) group, for the treatment of angina pectoris, hypertension and for treatment after heart attack.

Therapeutic group
Selective beta 1 receptor blocker.

2. BEFORE USING THE MEDICINE

- Do not use the preparation if you are suffering from:**

 - a known sensitivity to any of its ingredients
 - or have suffered in the past from heart problems, especially uncontrollable heart failure, second- or third-degree heart block, very slow or irregular heartbeats, very low blood pressure or severe blood circulation disturbances
 - cardiogenic shock, manifested by significant reduction in blood pressure, pallor, agitation, rapid and weak pulse, clammy skin, reduced consciousness
 - low blood pressure
 - you are being treated with intravenous verapamil or diltiazem
 - pheochromocytoma (high blood pressure caused by a tumor usually located close to the kidney)
 - metabolic acidosis (abnormal levels of blood acidity)
 - severe asthma or a severe pulmonary disease (e.g., severe and chronic obstructive pulmonary diseases)
 - This preparation is not intended for children

Special warnings regarding use of the medicine

Before starting treatment, tell the doctor if you are suffering, or have suffered in the past, from the following health problems:

- Asthma or other allergic reactions such as insect bites. If you suffered in the past from asthma or wheezing or other respiratory problems, do not take the tablets unless you have clarified these effects with the doctor who prescribed this medicine for you.
- Prinzmetal's angina-type chest pain.
- Cold sensation in the fingers or toes, pain, cramps or numbness/fatigue in the legs when walking – these conditions may worsen with use of this medicine.
- Uncontrolled heart failure or first-degree heart block, ischemic heart disease, or impaired heart function.
- Diabetes – Normiten may change your regular reaction to a decrease in blood sugar, usually manifested by increased heartbeat.
- If you have thyrotoxicosis (a disease caused by an overactive thyroid gland) – Normiten may mask the symptoms of thyrotoxicosis such as rapid heartbeat, tremor or excessive sweating.
- If you have kidney problems. In this case, you may have to undergo certain tests during the course of treatment.
- You have a slow heartbeat (50-55 beats per minute).
- You are elderly – an adjustment of the dosage should be considered.
- You suffer from psoriasis.
- You are suffering, or have suffered in the past, from allergic reactions – Normiten may increase them; use of adrenaline may not be effective in treating these allergic reactions.

If you are unsure, consult a doctor or pharmacist if you are suffering from any of the above-mentioned effects.

Additional warnings

If you come to the hospital or are due to undergo surgery, inform the anesthesiologist and the medical staff that you are taking this medicine, since taking anesthetics in combination with Normiten may cause a reduction in blood pressure.

If you are due to undergo an x-ray that involves use of a contrast agent (containing iodine), tell the doctor or dentist that you are taking Normiten.

If you are taking calcium channel blockers, such as verapamil, diltiazem and nifedipine (for treatment of high blood pressure or angina pectoris), tell the doctor before taking Normiten.

If you are in doubt, consult the doctor or pharmacist.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular inform the doctor or pharmacist if you are taking:

- Clonidine (for treatment of hypertension or prevention of migraine). If you take clonidine with Normiten, do not stop taking clonidine or Normiten before receiving instructions from the doctor.
- Do not take concomitantly with calcium channel blockers such as verapamil, nifedipine or diltiazem and consult the doctor or pharmacist if you are taking these medicines (used to treat hypertension or chest pain). (see Additional warnings)
- Disopyramide, lidocaine, procainamide, quinidine or amiodarone (for heart rate disturbances)
- Digoxin (for heart failure)
- Adrenaline (heart stimulant)
- Ibuprofen and indomethacin (for pain and inflammation)
- Insulin and oral medicines to lower sugar level
- Medicines that reduce nasal congestion or other cold medicines (including non-prescription medicines you can buy at a pharmacy). If you are taking other medicines, including medicines obtained at a pharmacy and herbal medicines, inform the doctor.
- Alpha blockers such as prazosin, terazosin, alfuzosin (to lower blood pressure or to treat Raynaud's disease)
- Monoamine oxidase inhibitors or tricyclic antidepressants (e.g., amitriptyline – for depression)
- Isoprenaline or dobutamine (to dilate blood vessels)
- Barbiturates (to treat insomnia, epilepsy or as an anesthetic, e.g., phenobarbital)
- Phenothiazines (e.g., chlorpromazine to treat mental illnesses)
- Baclofen (for muscle spasms)
- Ampicillin (antibiotic)
- Diuretics
- Vasodilators
- Suxamethonium and tubocurarine (peripheral muscle relaxants) – use of these preparations together with Normiten may increase the muscle relaxing effect.

Use of the medicine and alcohol consumption

Avoid or reduce alcohol consumption while taking this medicine since your blood pressure may significantly drop as a result of the combination.

Pregnancy and breastfeeding

Consult a doctor before using this medicine if you are pregnant, are considering becoming pregnant, or are breastfeeding.

Use in children

This medicine is not intended for use in children.

Driving and use of machinery

This medicine may cause dizziness, fatigue and blurred vision. If these effects occur, do not drive or operate machinery.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain. The dosage and treatment regimen will be determined by the doctor only. Unless instructed otherwise by the doctor, the usual dosage is as follows:

For treatment of angina pectoris

Initially, one 50 mg tablet once a day; can be gradually increased, as necessary, to 100 mg per day, after one week.

For treatment of hypertension

Initial dosage of 25-50 mg once a day; after two weeks, can be raised, as necessary, to 100 mg per day.

Treatment after heart attack

In patients who suffered from a heart attack, a long-term prophylactic dosage of 100 mg per day is recommended.

The elderly and patients with impaired kidney function

The doctor will consider adjustment of the dosage.

Do not exceed the recommended dose.

The medicine is not intended for use in children.

Try to take the tablet at the same time every day.

It is very important not to skip any dose, especially when the dosage is once a day.

Use this medicine at specified time intervals, as determined by the attending doctor.

Do not chew or crush!

Normiten 100 mg: do not halve.

Normiten 25 mg and 50 mg: can be halved on the score line.

Swallow the tablets whole with water.

If you took an overdose of the medicine, or if a child swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine.

Overdose effects: reduced pulse and blood pressure, chest tightness due to contraction of the respiratory tract muscles, or sometimes fainting.

If you forgot to take this medicine

If you forgot to take this medicine at the scheduled time, do not take a double dose.

Take the next dose at the regular time and consult a doctor.

Do not take two doses together! If you took, consult the doctor or pharmacist.

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health condition, do not stop treatment with the medicine without first consulting the doctor or pharmacist.

If you stop taking this medicine

Do not stop taking this medicine against the doctor's orders. In certain cases, discontinuation of treatment will be performed gradually over 7-14 days, while under monitoring.

How can you contribute to the success of the treatment?

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Normiten may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop treatment and refer to a doctor immediately if you experience any of the following side effects:

- Occurrence of allergic reactions (signs include: lumps on the skin, swelling of the face, lips, mouth, tongue or throat)
- Irregular heartbeat, dizziness, tiredness or fainting – may be signs of heart block
- While taking this preparation, you may experience slowed heartbeat; this is a normal effect, but if you are concerned, refer to the doctor.
- Shortness of breath or swollen ankles – may be signs of heart failure or worsened heart failure

Additional side effects that may occur

Common side effects (affect less than 1 in 10 patients)

- While taking this preparation, you may experience a slowed heartbeat; this is a normal effect, but if you are concerned, refer to the doctor.
- Cold hands and legs
- Diarrhea
- Feeling sick (nausea)
- Stomach pain
- Heartburn
- Digestion problems
- Constipation
- Tiredness and aching muscles
- Sweating

Uncommon side effects (affect less than 1 in 100 patients)

- Sleep disturbances
- Increase in levels of liver enzymes

Rare side effects (affect less than 1 in 1,000 patients)

- Heart block (manifested by dizziness, irregular heartbeat, tiredness or fainting)
- Numbness and cramps in the fingers, accompanied by warmth and pain (Raynaud's syndrome)
- Mood changes
- Nightmares
- Confusion, anxiety or fear
- Changes in personality (psychoses – mental disorders) or hallucinations
- Headache
- Dizziness (particularly when standing up)
- Tingling in the hands
- Impotence
- Dry mouth
- Dry eyes
- Blurred vision
- Thinning of the hair
- Skin rash
- Tendency to easily develop bruise marks
- Purple marks or bruises on the skin
- Jaundice (manifested by yellowing of the skin or eyes)
- Low blood pressure
- Insomnia
- Reduced heart function
- Changes to some of the parts and cells of the blood. The doctor may refer you for blood tests, at his discretion, to check whether Normiten has any effect on your blood system.
- Depression

Very rare side effects (affect less than 1 in 10,000 patients)

- Changes to some of the parts and cells of the blood. The doctor may refer you for blood tests, at his discretion, to check whether Normiten has any effect on your blood system.

Conditions that may get worse

If you have any of the following problems, they may get worse at the beginning of treatment (rare: affecting less than 1 in 1,000 patients)

- Psoriasis (a skin disease)
- Shortness of breath, swollen ankles (in patients with heart failure)
- Breathing problems
- Asthma or breathing problems
- Blood circulation disturbances
- Cramping causing limping

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor immediately.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

Do not use the medicine after the expiry date (Expiry date) that appears on the package. The expiry date refers to the last day of that month.

Store in a dry and dark place, below 25°C.

Do not discard medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Magnesium carbonate heavy, starch, magnesium stearate, sodium lauryl sulphate, gelatin.

Sodium content per one tablet:

Normiten 25 mg: 0.13 mg

Normiten 50 mg: 0.26 mg

Normiten 100 mg: 0.52 mg

What the medicine looks like and the contents of the package

Normiten 25 mg: a white to off-white, octagonal tablet with a score line.

Normiten 50 mg: a white to off-white, octagonal tablet with a score line.

Normiten 100 mg: a white to off-white, octagonal tablet.

License holder

Abic Ltd., P.O.B. 8077 Netanya.

Manufacturer and address

Manufactured by Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva.

This leaflet was checked and approved by the Ministry of Health on 7/10/2014.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Normiten 25 mg:

104.02.28834.00; 104.02.28834.01

Normiten 50 mg:

051.72.24149.00; 051.72.24149.01

Normiten 100 mg:

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