

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed with
a doctor's prescription only

Normiten®

25 mg Tablets

Composition
Atenolol 25 mg

Normiten®

50 mg Tablets

Composition
Atenolol 50 mg

Normiten®

100 mg Tablets

Composition
Atenolol 100 mg

For information on inactive and allergenic ingredients, see section 2 "Important information about some of the ingredients of the medicine" and section 6 – "Further Information".

Read the 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.

The medicine is not intended for use in children.

1. WHAT IS THE MEDICINE INTENDED FOR?

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

Therapeutic group

Selective beta 1 receptor blocker.

2. BEFORE USING THE MEDICINE

Do not use Normiten if:

- You are sensitive (allergic) to atenolol or to any of the additional ingredients contained in the medicine (see section 6).
- You have suffered in the past from any of the following heart problems:
 - Heart failure which is not under control (usually causes shortness of breath and swelling of the ankles).
 - Second- or third-degree heart block (a condition that may be treated by a pacemaker).
 - Very slow or irregular pulse/heartbeat, very low blood pressure or severe circulatory disturbances.
- You have a type of cancer called pheochromocytoma that is not being treated. This is a tumor that is usually located near the kidney, causing high blood pressure. If your pheochromocytoma is being treated, your doctor will give you another medicine, called an alpha-blocker, to take in addition to Normiten.
- You have metabolic acidosis (higher than normal blood acid levels).

Special warnings regarding use of the medicine:

Treatment with atenolol is not recommended for patients with bronchospastic respiratory diseases (such as severe asthma). If it is determined that this is the right treatment for you, the treatment will be given at the lowest possible dosage. Consult with the doctor regarding the necessity of having a bronchodilator preparation available.

Before starting treatment, tell the doctor if:

- You suffer from asthma, wheezing, other similar respiratory problems, or if you develop allergic reactions, for example, to insect stings. If you have suffered in the past from asthma or wheezing, do not take the medicine without first consulting the doctor.
- You suffer from a type of chest pain called Prinzmetal's angina.
- You suffer from impaired blood circulation or controlled heart failure.
- You suffer from first-degree heart block.
- You suffer from diabetes – the medicine may change your reaction to a decrease in blood sugar level. You may feel an increase in heartbeat.
- You suffer from thyrotoxicosis (a disease caused by an overactive thyroid gland). Normiten may mask the symptoms of thyrotoxicosis.
- You suffer from kidney problems. In this case, you may be required to undergo certain tests during the course of treatment.

If you are not sure if the above conditions apply to you, consult the doctor or pharmacist before taking Normiten.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. This is because Normiten may affect the way some other medicines work and some medicines may affect Normiten.

In particular, inform the doctor or pharmacist if you are taking:

- Clonidine (for treatment of hypertension or migraine). If you are taking clonidine with Normiten, do not stop taking clonidine unless your doctor instructs you to do so. If you have to stop taking clonidine, your doctor will give you careful instructions how to do so.
- Verapamil, nifedipine or diltiazem (used for treatment of hypertension or chest pain).
- Disopyramide, quinidine or amiodarone (for irregular heart rhythm).
- Digoxin (for heart problems).
- Adrenaline, also known as epinephrine (a medicine that stimulates heart activity).
- Ibuprofen or indomethacin (for pain and inflammation).
- Insulin and oral medicines to treat diabetes.
- Nasal or sinus decongestants or other cold medicines (including non-prescription medicines bought at a pharmacy).

Operations

If you go to hospital to undergo an operation, inform the anesthesiologist or medical staff that you are taking Normiten, since administration of certain anesthetics during treatment with Normiten may cause a drop in blood pressure (hypotension).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult the doctor or pharmacist before using the medicine.

Use in children

This medicine is not intended for use in children.

Driving and using machines

- This medicine is unlikely to affect your ability to drive, or operate tools or machines. However, it is best to wait to see how the medicine affects you before trying to undertake these activities.
- If you feel dizzy or tired while taking the medicine, do not drive or use any tools or machines.

Important information about some of the ingredients of the medicine

This medicine contains less than 23 mg sodium per tablet and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose.

The medicine is not intended for use in children.

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

It is very important not to skip any dose, especially when the dosage is once a day. Use this medicine at set 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: may be halved on the score line.

Swallow the tablets whole with water.

If you took a higher dosage

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

If you forgot to take the medicine

If you forgot to take this medicine at the required time, take a dose as soon as you remember. However, if it is almost time for the next dose, skip the forgotten dose. Do not take a double dose to make up for a forgotten dose.

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

If you stop taking the medicine

Do not stop taking this medicine before consulting the doctor. In some cases, discontinuation of treatment will be performed gradually.

How can you contribute to the treatment success?

Do not take medicines in the dark! Check the label and the dose each time you take a 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.

Allergic reactions:

If you develop an allergic reaction, refer to a doctor immediately. The signs can include lumps on your skin or swelling of your face, lips, mouth, tongue or throat.

Additional side effects

Common side effects (affects up to 1 in 10 patients)

- When taking the preparation, you may experience a slowed heartbeat; this is a normal effect, but if you are concerned, refer to a doctor.
- Cold hands and feet.
- Diarrhea.
- Nausea.
- Tiredness.

Uncommon side effects (affects up to 1 in 100 patients)

- Sleep disturbances.

Rare side effects (affects up to 1 in 1,000 patients)

- Heart block (may cause dizziness, irregular heartbeat, tiredness or fainting).
- Numbness and cramps in the fingers, accompanied by warmth and pain (Raynaud's disease).
- Mood changes.
- Nightmares.
- Confusion.
- Changes in personality (psychoses – mental disorders) or hallucinations.
- Headache.
- Dizziness (especially upon standing up).
- Tingling in the hands.
- Inability to achieve an erection (impotence).
- Dry mouth.
- Dry eyes.
- Vision disturbances.
- Thinning of the hair.
- Skin rash.
- Reduced number of blood platelets (which may make you bruise more easily).
- Purplish marks on your skin.
- Jaundice (manifested by yellowing of the skin or the whites of the eyes).

Very rare side effects (affects up to 1 in 10,000 patients)

- Changes to some of the cells and other blood components. The doctor may refer you for occasional blood tests, to check whether Normiten has had any effect on your blood system.

Side effects of unknown frequency (the frequency cannot be estimated from available data)

- Lupus-like condition (a disease where the immune system produces antibodies that mainly attack the skin and joints).
- Depression.

Conditions which may worsen

If you suffer from any of the following problems, they may worsen at the beginning of Normiten treatment. These rarely occur and affect less than 1 in 1,000 people

- Psoriasis (a skin disease).
- Shortness of breath, swelling of the ankles (in patients with heart failure).
- Asthma or breathing problems.
- Blood circulation disturbances.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an 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 into 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.

What the medicine looks like and the contents of the package

Normiten 25 mg: an octagonal, white to off-white tablet. "Abic" is debossed on one side and "25" with a score line on the other side. Each package contains 30 tablets packed in blisters (trays).

Normiten 50 mg: an octagonal, white to off-white tablet. "Abic" is debossed on one side and "50" with a score line on the other side. Each package contains either 12, 28, 30, 480 or 500 tablets packed in blisters (trays).

Normiten 100 mg: an octagonal, white to off-white tablet. "Abic" is debossed on one side and "100" on the other side. Each package contains either 12, 24, 28, 30, 480 or 500 tablets packed in blisters (trays).

Not all package sizes may be marketed.

License Holder

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

Name of Manufacturer and its Address

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

This leaflet was revised in September 2021 according to MOH guidelines.

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

Normiten 25 mg: 104.02.28834

Normiten 50 mg: 051.72.24149

Normiten 100 mg: 045.35.24916

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