

Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Normalol® Tablets 25, 50, 100 mg

Active ingredient: Each tablet contains atenolol at a dose of 25, 50 or 100 mg respectively.

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist. This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar.

The medicine is not intended for use in children.

1. What is the medicine intended for?

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

Therapeutic group: Selective beta-1 receptor blocker.

2. Before using the medicine

Do not use the medicine if:

- you are hypersensitive (allergic) to the active ingredient (atenolol) or to any of the other ingredients this medicine contains (see section 6).
- you have suffered in the past from any of the following heart problems:
 - heart failure which is not under control (which usually causes shortness of breath and swelling of the ankles)
 - second or third degree heart block (a condition which can be treated by a pacemaker)
 - very slow or irregular pulse, very low blood pressure or severe circulation disorders.
- you have a type of tumor called pheochromocytoma that is not being treated. This is a tumor usually located near the kidney that causes high blood pressure. If your phaeochromocytoma is being treated, your doctor will give you a different medicine called an alpha-blocker to take in addition to **Normalol**.
- You suffer from metabolic acidosis (higher than normal blood acid levels).

Special warnings regarding the use of the medicine:

Treatment with atenolol is not recommended for patients suffering from bronchospastic respiratory

diseases (such as severe asthma). If it was decided that this is the appropriate treatment for you, treatment will be given at the lowest possible dosage. Consult the doctor about the necessity of an available bronchodilator preparation.

Before the treatment with Normalol, tell the doctor if:

- you suffer from asthma, wheezing-like breathing sounds, other similar breathing problems or if you develop allergic reactions for example to insect stings. If you have suffered in the past from asthma or wheezing-like breathing sounds, 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 poor 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 the blood sugar level. You may feel an increase in heart rate.
- you suffer from thyrotoxicosis (a disease caused by an overactive thyroid gland). **Normalol** 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, you should consult a doctor or pharmacist before taking **Normalol**.

Drug interactions

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, as Normalol may affect the activity of certain other medicines, and certain other medicines may affect Normalol.

Especially tell the doctor or pharmacist if you are taking:

- Clonidine (for treatment of hypertension or migraine). If you are taking clonidine and **Normalol** concomitantly, do not stop taking clonidine unless the doctor instructed you to do so. If you need to stop taking Clonidine the doctor will give you precise instructions on how to do so.
- Verapamil, nifedipine or diltiazem (for treatment of hypertension or chest pain).
- Disopyramide, quinidine or amiodarone (for treatment of an irregular heartbeat).
- Digoxin (for treatment of heart problems).
- Adrenaline which is also known as epinephrine (a medicine that stimulates heart function).

- Ibuprofen or indometacin (for treatment of pain and inflammation).
- Insulin and oral medicines for treatment of diabetes.
- Medicines that decrease nasal or sinus congestion or other cold medicines (including medicines you can buy in the pharmacies without a doctor's prescription).

Surgery

If you go to a hospital to undergo surgery, you must tell the anaesthesiologist or medical staff that you are taking **Normalol**, as administration of certain anaesthetics while being treated with **Normalol** may cause a decrease in blood pressure (hypotension).

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using this medicine.

Use in children

This medicine is not intended for use in children.

Driving and using machines

- It is likely that this medicine will not affect your ability to drive or to operate tools or machines. However, it is preferable to wait and see how the medicine affects you before attempting to carry out these actions.
- If you feel dizziness or fatigue when taking the medicine, do not drive or use tools or machines.

Important information about some of the ingredients of this medicine

This medicine contains lactose. If you have been told by a doctor in the past that you have an intolerance to certain sugars, consult a doctor before starting treatment with this medicine.

This medicine contains less than 1 mmol (23 mg) sodium per tablet that is to say essentially "sodium-free".

3. How to use this medicine

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

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

Do not exceed the recommended dosage. 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 daily.

Use this medicine at regular intervals as determined by the doctor.

Method of administration: The tablet can be halved, there is no information regarding crushing or chewing.

If you have taken a higher dosage

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

If you forgot to take the medicine

If you forgot to take this medicine at the designated 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.

Continue with 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 the medicine

Do not stop taking this medicine before consulting the doctor. In certain cases, stopping the treatment will be carried out gradually.

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 the use of this medicine, consult the doctor or pharmacist.**

4. Side effects

Like any medicine, the use of **Normalol** 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 immediately to the doctor. The signs can include lumps on the surface of the skin or swelling of the face, lips, mouth, tongue or throat.

Additional side effects

Common side effects (effects that appear in 1-10 out of 100 users):

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

Uncommon side effects (effects that appear in 1-10 out of 1,000 users):

- Sleep disorders

Rare side effects (effects that appear in 1-10 out of 10,000 users):

- Heart block (may cause dizziness, irregular heartbeat, fatigue or fainting)
- Numbness and cramps in the fingers accompanied by a sensation of heat and pain (Raynaud's disease)
- Mood changes
- Nightmares
- Confusion
- Personality changes (psychoses – mental disorders) or hallucinations
- Headache
- Dizziness (especially when you stand up)
- Tingling in the hands
- Inability to achieve an erection (impotence)
- Dry mouth
- Dry eyes
- Visual disturbances
- Hair loss
- Skin rash
- Decrease in the number of platelets in the blood (which may cause you to be more easily bruised)
- Purple marks on the skin
- Jaundice (expressed by yellowing of the skin or the whites of the eyes)

Very rare side effects (effects that appear in less than 1 out of 10,000 users):

- Changes in some of the cells and additional components of the blood. The doctor may refer you to take blood tests occasionally, in order to check whether **Normalol** is having any effect on your blood system.

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

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

Conditions that may worsen:

If you suffer from any of the following problems, they may worsen at the beginning of the treatment with **Normalol**. This occurs rarely (effects that appear in 1-10 users out of 10,000):

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

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health via the link

"דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link: <http://sideeffects.health.gov.il>

5. How to store the medicine

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** do not store above 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

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

Lactose monohydrate, maize starch, sodium starch glycolate, cellulose, glyceryl behenate, povidone, carmellose sodium, magnesium stearate, silica colloidal anhydrous.

What the medicine looks like and what the package contains:

Round, white, scored tablet.

Approved package sizes for **Normalol 25/50/100:** 10/30 tablets.

Not all package sizes may be marketed.

Drug registration number at the national drug registry of the Ministry of Health:

Normalol 25: 104-19-28700-00

Normalol 50: 052-40-26223-00

Normalol 100: 052-39-26224-00

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Manufacturer and registration holder: **Dexcel® Ltd.**

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