PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Neobloc
Film-coated Tablets

Composition:
Each film-coated **Neobloc** tablet contains:
Metoprolol Tartrate 100 mg
For the list of inactive and allergenic ingredients in the preparation, please see section 6 "Further information". Also see in section 2 "Important information about some of the ingredients of the medicine".
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 children.

1. WHAT IS THE MEDICINE INTENDED FOR?
Therapeutic activity: Selective beta receptor blocker for the treatment of hypertension, angina pectoris and irregular heart rhythm, prevention of migraine and prevention of myocardial reinfarction.
Therapeutic group: selective beta receptor blocker.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- You are sensitive (allergic) to metoprolol, to other beta blockers, or to any of the additional ingredients contained in the medicine (see section 6 "Further information").
- You have heart conduction problems or heart rhythm disturbances.
- You have severe or uncontrolled heart failure.
- You have cardiogenic shock.
- You have blocked blood vessels, including blood circulation problems (a phenomenon that can cause tingling or pallor/bluishness in the hands or feet).
- You have a slow heart rate or have suffered a heart attack and as a result now have a very slow heart rate.
- You suffer from a sensation of pressure and pain at rest (Prinzmetal's angina).
- You have an untreated pheochromocytoma (high blood pressure due to a tumor near the kidney).
- You have increased acidity of the blood (metabolic acidosis).
- You have low blood pressure.
- You have or have had breathing difficulties or asthma, including chronic obstructive pulmonary disease (COPD), characterized by cough, wheezing or breathlessness, secretion of mucus and an increase in respiratory tract infections.
- You have diabetes characterized by recurrent episodes of low blood sugar levels (hypoglycemia).
- You have liver or kidney disease or failure.
- You are being treated by injection with other medicines for hypertension, especially verapamil, diltiazem or disopyramide.

Special warnings regarding use of the medicine
Before treatment with Neobloc, tell the doctor if:
- You have suffered in the past from allergic reactions, for example, to insect stings, food or other substances.
- You have diabetes. (**Neobloc** can mask symptoms of low blood sugar levels).
- You have monitored and treated heart failure.
- You have a slow heart rate or a disturbance of blood circulation in the blood vessels.
- You have a treated pheochromocytoma (increased blood pressure due to a tumor near the kidney).
- You have, or have suffered in the past from psoriasis (characterized by a severe skin rash).
- You have cirrhosis of the liver.
- You are elderly.
- You have myasthenia gravis (which manifests as severe muscle weakness).
- You suffer from dry eyes.

Additional warnings:
If you are due to undergo an operation (including dental) or any procedure involving anesthesia, inform the anesthesiologist or dentist that you are taking this medicine, to prevent a condition in order to avoid a situation where the heart rate is too slow.
Children and adolescents
Do not give the medicine to children.
Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Do not use the medicine if you are taking:
- Monoamine oxidase inhibitors (MAOIs), usually used to treat depression.
- Other antihypertensives, such as verapamil, nifedipine and diltiazem.
- Disopyramide or quinidine to treat heart rhythm disorders (arrhythmia).

In particular, inform the doctor or pharmacist if you are taking, or have taken in the past:
- Cimetidine (to treat gastric ulcer).
- Hydralazine, clonidine or prazosin (to treat hypertension).
- Amiodarone, propafenone (to treat heart rhythm disturbances).
- Tricyclic or SSRI antidepressants.
- Barbiturates (to treat epilepsy).
- Phenothiazines (to treat mental illnesses).
- Anesthetics (e.g., cyclopropane or trichlorethylene).
- Aldesleukin (to treat cancer, primarily kidney cancer).
- Alprostadil (to treat impotence).
- Anti-anxiety medicines or hypnotics (e.g., temazepam, nitrazepam, diazepam).
- Indomethacin or celecoxib (nonsteroidal anti-inflammatory drugs [NSAIDs]).
- Rifampicin (antibiotic) or terbinafine (to treat infections caused by fungi).
- Estrogens – in birth control pills or in hormone replacement therapy.
- Corticosteroids (e.g., hydrocortisone, prednisolone).
- Other beta blockers, including those given in eye drops.
- Adrenaline (epinephrine) or noradrenaline (norepinephrine) used for anaphylactic shock or sympathomimetic medicines.
- Medicines used to treat diabetes.
- Lidocaine (used for local anesthesia).
- Moxisylyte (used for Raynaud's phenomenon).
- Mefloquine (to treat malaria).
- Tropisetron (to prevent nausea and vomiting).
- Xanthines, such as aminophylline or theophylline (to treat asthma).
- Medicines to treat migraine, such as ergotamine.
- Cardiac glycosides, such as digoxin (used to treat heart conditions).
- Hydroxychloroquine (also used to treat rheumatoid arthritis).
- Diphenhydramine (e.g., sedative antihistamines).

Use of the medicine and alcohol consumption
It is recommended not to drink beverages containing alcohol during the course of treatment with the medicine, since the combination of **Neobloc** with alcohol may increase the blood pressure-lowering effect.
Pregnancy and breastfeeding
It is not recommended to use Neobloc tablets during pregnancy or when breastfeeding. If you are pregnant, breastfeeding, think you are pregnant or are planning to become pregnant, consult the doctor about using the medicine.
Driving and use of machinery
Use of this medicine may cause fatigue and dizziness. If this is the effect, patients should not drive or operate machinery.
Important information about some of the ingredients of the medicine
Neobloc tablets contain lactose.
If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medical preparation (see also section 6 "Further information").

3. HOW SHOULD YOU USE THE MEDICINE?
Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only.
The usual dosage is generally:
Hypertension: The usual starting dosage is generally 100 mg metoprolol tartrate per day (one **Neobloc** tablet). The dosage may be increased to 200 mg (two **Neobloc** tablets) per day, as a single dose or in divided doses.
Angina pectoris: 50-100 mg metoprolol tartrate (half a tablet to one tablet of **Neobloc**), two or three times a day.
Heart rhythm disturbances: 50 mg metoprolol tartrate (half a **Neobloc** tablet), two or three times a day. The dosage may be increased up to 300 mg (3 **Neobloc** tablets) per day, in divided doses.
Heart attack: 50 mg metoprolol tartrate (half a **Neobloc** tablet) every 6 hours. The recommended maintenance dose is 200 mg per day, in divided doses. The medicine must be taken for at least 3 months.
Prevention of migraines: 100-200 mg metoprolol tartrate (one to two tablets of **Neobloc**), in divided doses (morning and evening).
Use in patients with liver or kidney function disorders: It may be necessary to adjust the dosage. Consult the doctor.
Do not exceed the recommended dose.
Swallow the medicine with a little water.
If necessary, the tablet can be halved for immediate use. There is no information about crushing or chewing the tablet.
If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. Symptoms of overdose are low blood pressure (characterized by fatigue and dizziness), slow pulse, electrical conduction disorders of the heart, cardiac arrest, shortness of breath, loss of consciousness, coma, nausea, bluish color of the skin, low blood sugar level, high blood potassium level.
If you forgot to take this medicine at the designated time, take a dose as soon as you remember, but if it is almost time to take the next dose, skip the forgotten dose and take the next dose at the designated time and consult a doctor. Never take two doses together!
Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor or pharmacist.
Do not stop using the medicine suddenly.
If you stop taking the medicine suddenly, there may be an immediate exacerbation of your condition. Such discontinuation of the medicine may cause worsening of heart failure or increased risk of heart attack. A change in the dosage or discontinued use of the medicine must be carried out in consultation with the doctor.
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 with the doctor or pharmacist.

4. SIDE EFFECTS
As with any medicine, use of **Neobloc** 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.
Discontinue treatment and contact your doctor immediately if you experience the following symptoms:
An allergic reaction, such as itching, breathing difficulties or swelling of the face, lips, throat or tongue.
Refer to a doctor if you experience the following effects:
Common side effects (effects that occur in one user in 10):
Tiredness, dizziness, headache, slow heart rate, feeling faint upon standing up due to low blood pressure, shortness of breath with or without strenuous physical activity, nausea, stomach pain.
Rare side effects (effects that occur in one user in 1,000):
Depression, nightmares, nervousness, anxiety, sexual dysfunction or reduced sexual drive, inability to think clearly, sleepiness or sleeping difficulties, tingling or prickling sensation, difficulty breathing, heart failure, irregular heart rate, palpitations, fluid retention causing swelling, Raynaud's phenomenon (causing pain, numbness, sensation of cold and bluing of the fingers), diarrhea or constipation, skin rash, muscle cramps.
Very rare side effects (effects that occur in less than one user in 10,000):
Changes in the results of blood tests, effects on blood clotting causing easy or unexplained bruising, changes in personality, confusion, hallucinations, visual disturbances, irritated or dry eyes, ringing in the ears, hearing loss is possible when taking high doses of the medicine, heart conduction problems, chest pain, gangrene in patients with severe blood circulation problems, runny nose, dry mouth, weight gain, increased sensitivity to light, increased sweating, hair loss, onset or worsening of psoriasis, joint inflammation (arthritis), sexual dysfunction or libido disorders, changes in liver function blood test results, taste disorders.
Side effects of unknown frequency (effects whose frequency has not yet been determined):
Worsening or development of limping, liver inflammation – hepatitis (symptoms include fever, nausea and vomiting and yellowing of the skin or whites of the eyes), Peyronie's syndrome (unusual curvature of the penis), symptoms of hyperthyroidism or of low blood sugar levels may be hidden, increase in blood fat level or decrease in cholesterol, retroperitoneal fibrosis (symptoms include lower back pain and high blood pressure, occurrence of antinuclear antibodies independent of systemic lupus erythematosus [SLE]).
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
Additionally, you can report to "Unipharm Ltd.".

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 and sight of children and/or infants in order 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 (exp. date) that appears on the package. The expiry date refers to the last day of that month.
Storage conditions: Store below 25°C and in a place protected from light.

6. FURTHER INFORMATION
In addition to the active ingredient, the medicine also contains:
Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, carmellose sodium LS, povidone, talc, magnesium stearate, colloidal silicon dioxide, opadry OY-L-30919 (blue).
Each **Neobloc** tablet contains 35 mg lactose.
What the medicine looks like and the contents of the package:
Neobloc is marketed in packages of 10, 15, 20, 30, 50 or 100 tablets packaged in a tray (blister). Not all package sizes may be marketed.
Neobloc are round, blue, biconvex, film-coated tablets with a score line on one side.
Registration holder and address: Unipharm Ltd., P.O.Box 21429, Tel Aviv, 6121301.
Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 010 52 24172 01
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