

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

The medicine is dispensed with a doctor's prescription only

NORLIP

Tablets

Composition:

Each **Norlip** tablet contains:

Bezafibrate 200 mg

For a list of inactive and allergenic ingredients in the preparation, see in 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.

The medicine has been prescribed to treat 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 preparation is not intended for use in children.

1. WHAT IS THE MEDICINE INTENDED FOR?

- Primary hyperlipidemia [congenital], when diet alone or lifestyle changes, such as increased exercise or weight reduction do not lead to an adequate response.
- Secondary hyperlipidemia [acquired], e.g., severely high blood triglyceride level (hypertriglyceridemia), when sufficient improvement does not occur after treatment of the underlying disease (e.g., diabetes).

Therapeutic group: Fibrates.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient bezafibrate or to any of the additional ingredients contained in the medicine (see section 6 "Further Information").
- you are sensitive (allergic) to other fibrates or you have developed sensitivity to sunlight or artificial light (e.g., tanning beds) during treatment with these medicines.
- you are taking medicines from the statin family (e.g., atorvastatin) and are suffering from the following conditions that may increase the risk of developing a muscle disease (weakness, muscle tissue breakdown or muscle pain):
 - impaired kidney function.
 - an underactive thyroid (hypothyroidism).
 - severe infection.
 - trauma.
 - surgery.
 - changes in hormone or chemical levels in your body (seen in blood tests).

- high alcohol consumption.
- you are being treated with dialysis.
- you have liver disease.
- you have gallbladder disease.
- you are suffering from nephrotic syndrome (a kidney disorder).
- you have severely impaired kidney function.

Special warnings regarding use of the medicine

Before treatment with Norlip, tell the doctor if:

- you have an abnormal level of fats in the blood, caused by:
 - uncontrolled type 2 diabetes mellitus.
 - an underactive thyroid (hypothyroidism).
 - nephrotic syndrome (a kidney disorder).
 - an abnormal level of protein in the blood.
 - obstructive liver disease.
 - medication.
- you are addicted to alcohol.
- you are suffering from any of the following conditions that may increase the risk of you developing muscle disease (weakness, muscle tissue breakdown or muscle pain):
 - impaired kidney function.
 - an underactive thyroid (hypothyroidism).
 - severe infection.
 - trauma.
 - surgery.
 - changes in hormone or chemical levels in your body (seen in blood tests).
 - you consume large amounts of alcohol.
 - you are elderly (you are over 65 years of age).
 - you have a family history of muscle diseases.

Children and adolescents

Norlip is not intended for use in children.

Tests and follow-up

If you are suffering from impaired kidney function, your doctor may send you for periodic tests.

Drug interactions

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

- coumarin-type anti-coagulants e.g., warfarin (used to prevent blood clotting).
- medicines to treat diabetes, e.g., insulin.
- ciclosporin (used to suppress the immune system).
- anion exchange resins, such as colestyramine (used to lower cholesterol).
Take **Norlip** and anion exchange resins at least two hours apart from each other.
- statins, e.g., atorvastatin (used to lower cholesterol levels).
- monoamine-oxidase inhibitors (MAOIs) e.g., phenelzine (used to treat depression).

- estrogen or estrogen-containing preparations.

Use of the medicine and food

Take **Norlip** with water during or immediately after a meal.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think that you are pregnant or are planning a pregnancy, consult the doctor or pharmacist before taking the medicine.

Driving and using machinery

Use of **Norlip** may cause dizziness. Make sure you are not affected before driving or operating machinery.

Important information about some of the ingredients of the medicine

Norlip contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, and therefore is considered “sodium-free”.

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:

Adults: One tablet, three times a day (600 mg bezafibrate per day), after a meal.

Elderly: Your doctor may reduce the dosage depending on your kidney function.

Children: The preparation is not recommended for use in children.

Patients with impaired kidney function: Your doctor may decide to reduce the dosage, in accordance with your kidney function. Use of this medicine is contraindicated in dialysis patients.

Do not exceed the recommended dose.

Method of administration

Swallow the medicine with a little water, immediately after a meal.

If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the tablet.

Upon treatment in combination with anion exchange resins, wait at least two hours between taking the two preparations.

If you accidentally took a higher dosage

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. Signs of an overdose include abnormal muscle breakdown (pain, weakness or swelling of muscles) that may cause kidney problems (rhabdomyolysis).

If you forgot to take this medicine at the scheduled time, do not take a double dose to make up for the missed dose. Take the dose as soon as you remember and the next dose at the regular time and consult a doctor.

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 the doctor.

Do not take medicines in the dark! Check the label and the 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 **Norlip** 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.

Refer to a doctor immediately if you are suffering from the following effects:

- an allergic reaction (hypersensitivity) (uncommon) – swelling of the face, lips, tongue or throat, narrowing of the airways causing breathing or swallowing difficulties, skin reactions such as red or pale, irregular, raised patches accompanied by severe itching, itching, sensitivity to sunlight or artificial light (e.g., tanning beds).
- gallstones (very rare) – pain in the upper abdomen or yellowing of the skin or whites of the eyes (jaundice).
- abnormal muscle breakdown (rhabdomyolysis) (very rare) – pain, weakness or swelling in the muscles.
- blood and lymphatic system disturbances (very rare) – decreased level of platelets in the blood causing a disorder characterized by petechiae, bruising and colorless areas in the skin (thrombocytopenic purpura), decreased level of hemoglobin in the blood, increased levels of certain enzymes in your body (seen in blood tests), changes in the number and types of blood cells.
If you notice increased bruising, nosebleed, sore throat, infections, excessive tiredness, breathlessness on exertion or abnormal paleness of the skin, consult the doctor; there may be a need to perform blood tests.
- serious skin reactions (very rare) – irregular, red, round patches on the skin of the hands and arms (erythema multiforme), severe rash accompanied by flushing, fever, blisters or ulcers (Stevens-Johnson syndrome), severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis).

Additional side effects:

Common side effects (effects that occur in 1-10 in 100 users):

Decreased appetite, digestive disorders.

Uncommon side effects (effects that occur in 1-10 in 1,000 users):

Dizziness, headache, bloated feeling, nausea, diarrhea, abdominal pain, constipation, indigestion, biliary tract obstruction (cholestasis), itching, irregular raised pale or red patches with severe itching (urticaria), rash, sensitivity to sunlight or artificial light (e.g., tanning beds), hair loss (alopecia), muscle weakness, cramps or muscle pain (myalgia), acute kidney failure, erection disturbances, changes in the levels of certain enzymes in the body (seen in blood tests), increased blood levels of creatinine.

Rare side effects (effects that occur in 1-10 in 10,000 users):

Damage to nerve endings causing tingling, pins and needles, inflammation of the pancreas (pancreatitis), depression, sleeping difficulties.

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

Lung inflammation (interstitial lung disease), which causes shortness of breath (which can worsen over time) or cough (usually dry, without phlegm).

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 to avoid poisoning. Do not induce vomiting without explicit instructions from 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; Maize starch; Pregelatinized starch; Sodium starch glycolate; Magnesium stearate; Colloidal silicone dioxide; White coating blend (HPMC 2910/hypromellose, Titanium dioxide, Macrogol/PEG).

What the medicine looks like and the contents of the package:

Norlip is packaged in trays (blisters) which are inserted into a carton package. In each package there are 50, 60, 100 or 1,000 tablets. Not all package sizes may be marketed.

Norlip tablets are film-coated, white, round and biconvex, with a break line on one side.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

Registration holder and address: Unipharm Ltd., P.O. Box 16545, Tel Aviv, 6116401.

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

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