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, please see section 6: "Further information". See also 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.
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?

Therapeutic activity: to lower the level of cholesterol and triglycerides (lipids) in the blood, in cases where dietary treatment alone is not effective.
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).
- you are sensitive (allergic) to other fibrates or you have developed sensitivity to sunlight or artificial light (e.g., tanning beds) during the treatment with fibrates.
- you are taking medicines from the statin family (e.g., atorvastatin) and are suffering from the following conditions, which may increase the risk of developing a muscle disease (weakness, muscle tissue breakdown or muscle pain):
  - kidney dysfunction.
  - 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 a liver disease.
- you have a gallbladder disease.
- you are suffering from nephrotic syndrome (a kidney disease).
- 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 disease).
  - an abnormal level of protein in your blood.
  - obstructive liver disease.
  - medicines.
- you are addicted to alcohol.
- you are suffering from any of the following conditions which may increase the risk of you developing muscle disease (manifested by weakness, muscle wasting or 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 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. In particular, inform the doctor or pharmacist if you are taking:
- coumarins (anti-coagulants) e.g., warfarin (prevent the formation of blood clots).
- medicines to treat diabetes, e.g., insulin.
- ciclosporin (to suppress the immune system).
- anion exchange resins, such as colestyramine (used to lower cholesterol) – when used with **Norlip**, take at least two hours apart.
- statins, e.g., atorvastatin (to lower cholesterol levels).
- monoamine-oxidase inhibitors (MAOIs) e.g., phenelzine (to treat depression).
- estrogen or estrogen-containing preparations.

Use of the medicine and food
Take **Norlip** with a little water 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 before taking the medicine.

Driving and operating machinery
Use of **Norlip** may cause dizziness. Make sure you do not feel dizzy after taking the medicine and before driving or operating dangerous 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 recommended dosage is:
Adults: One tablet, three times a day (600 mg bezafibrate per day), after a meal.
Elderly: Your doctor may reduce the dose depending on your kidney function.
Children: The preparation is not recommended for use in children.
Patients with reduced kidney function: Your doctor may decide to change the dose, especially 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 cholestyramine powder, wait at least two hours between taking the two preparations.

If you accidentally took a higher dosage 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) which may cause kidney problems (rhabdomyolysis).

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

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 blisters 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 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 an effect 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) – red, round lesions 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):
Lack of 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, red or pale blisters accompanied by 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 (seen in blood tests), increased blood levels of creatinine.

Rare side effects (effects that occur in 1-10 in 10,000 users):
Nerve damage that causes a tingling sensation and numbness, 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; Opadry White Y-1-7000.

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 score line on one side.

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

Registration holder and address: Unipharm Ltd., P.O.Box 21429, Tel Aviv, 6121301.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Norlip: 046 05 23778 02

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unipharm ltd.

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