The format of this leaflet was defined by the Ministry of Health and its content was checked and approved by June 2013.

Patient leaflet in accordance with the pharmacists' regulations (preparations) 1986

This medicine is to be supplied upon physician's prescription only

Bezafibrate 400

Sustained Release Tablets

Each tablet contains:
Bezafibrate 400mg

*Inactive ingredients - see section 6 (Additional information) in this leaflet.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains summary information about this medicine. If you have any further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for treating your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

1. What is this medicine intended for?

Lowering of high fat levels in the blood (hyperlipidaemia) in patients where diet alone is insufficient.

Therapeutic group: Fibrates.

2. Before using this medicine

X Do not use this medicine if:

- You are allergic (hyper sensitive) to the active ingredients or to any of the other ingredients that this medicine contains
- You are sensitive to light when treated with fibrates
- You are taking medicines from the statin group (for example Atorvastatin)
- You are undergoing dialysis treatment
- You have a liver disease (except for fatty liver)
- You have a gallbladder disease with or without stones
- You suffer from a kidney malfunction
- You are pregnant or breath feeding

! Special warnings regarding to the use of the medicine

During the treatment with this medicine you should hold blood tests, liver function tests and tests to determine the level of lipids in your blood. During the treatment with this medicine, you should, in addition to modification of your eating habits, also increase physical exercise activity and reduce your weight, in accordance with your physician's instructions.

- If you are treated with estrogens, the treatment with bezafibrate should be reconsidered, as the levels of lipids in your blood may increase.
- Treatment with fibrates may cause toxicity of the muscle (rhabdomyolysis) with symptoms such as muscle pain, muscle weakness and muscle tissue breakdown. In such cases you have to stop taking the medicine immediately and consult your physician (see also "Side effects that require special attention").
- If you suffer from high level of triglycerides in the blood, an infection in the pancreas may develop.
- Treatment with this medicine is not recommended for children.

This medicine contains lactose.

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

- Do not use this medicine if you are taking medicines from the statin group, such as Atorvastatin (used for reducing cholesterol level)
- Coumarin – An anticoagulant medicine
- Medicines that reduce the levels of sugar in the blood, such as insulin or medicines from the Sulphonyl ureas group
- Ciclosporin **–** used to suppress the activity of the immune system
- Cholestyramine (used to reduce cholesterol level) combined with bezafibrate should be taken 2 hours apart.
- Monoamine oxidase inhibitors, such as Phenelzine (used to treat depression)
- Estrogens (including birth control pills)
- Phenytoin for the treatment of epileptic seizures

Using the medicine and alcohol consumption
If you consume large quantities of alcohol, you should consult your physician before you start taking this medicine.

Pregnancy and breastfeeding
Do not use the medicine if you are pregnant or breastfeeding.

Driving and using machines
Bezafibrate should have no effect on you capability to drive or to use machines. However, if you feel dizzy, you should be careful while driving or using machines.

Important information about some ingredients of the medicine
Bezafibrate contains lactose. Each tablet contains 40 mg lactose monohydrate.

3. How should you use the medicine?

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure. The dosage and treatment will be determined only by the physician.
The recommended dose is usually: one tablet a day (morning or evening).

Do not chew! Swallow the medicine with some water. You can split the tablet along the score line.
The medicine should be taken during or after meal.

Tests and follow-up
During the treatment with this medicine you should hold blood tests, liver and kidney function tests and tests to determine the level of lipids in your blood.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a hospital emergency room and bring the medicine package with you.
Symptoms of overdose include muscle tissue breakdown (pain, weakness, and swelling of the muscles) that can lead to problems in the kidneys.

If you forgot to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult the physician.

Persist with the treatment as recommended by the physician.

Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the physician or the pharmacist.

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.

4. Side effects

As with any medicine, use of Bezafibrate may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Side effects that require Special attention:

- Hypersensitivity – in very few cases a rare sensibility to the product was observed, that may be expressed in pressure in the chest, difficulty breathing, increased heart rate, skin reactions, edema, collapse of the cardio vascular system, trembling and fainting. If you develop an allergic reaction, you should stop taking this medicine and go straight to an emergency room.
- If you develop an acute skin reaction (Stevens Johnson syndrome, erythema multiform, toxic epidermal necrolysis), you should stop taking this medicine and seek immediately for medical help (very rare).
- If you develop stones in your gallbladder (symptoms are pain in the upper abdomen, yellowing of the skin and the white areas of the eyes), consult your physician immediately. (Frequency – rare cases).
- Rhabdomyolysis with symptoms such as muscle pain, muscle weakness and muscle tissue breakdown. In such cases you should stop taking the medicine immediately and seek for a medical help (very rare).

Other side effects:

- Skin and hair – allergic reaction on the skin, such as itching, urticaria (infrequent).
- Hair loss (rare).
- Allergic or toxic reaction to light, even after several months of treatment without any side effects. Symptoms – skin irritation, itchs, formation of blisters, skin changes. These symptoms are usually reversible. (Frequency – rare cases).
- Digestive system – gastrointestinal disorders, such as sensation of fullness, nausea and loss of appetite (infrequent).
- Nervous system – headaches and dizziness (infrequent). These symptoms are usually transient and do not require discontinuation of the treatment.

- Liver and gallbladder – impaired liver function (increase in liver enzymes, blockage of bile ducts). (Frequency –few cases).

- Blood system – slight decrease in hemoglobin levels and leukocytes count, decrease in platelets count and hemorrhages and pancytopenia (a simultaneous decrease in the number of red blood cells, white blood cells and platelets). (Were observed in few cases).
- Kidneys – slight elevations of serum creatinine levels, especially following a long term treatment.
- Blood tests – elevation in liver enzymes levels (transaminase). (Frequency – unknown).

If any of the side effects gets worse, or when you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Storage conditions:
  - Store at a temperature below 25˚C.
  - Store in the original package.

6. Additional information

- In addition to the active ingredients the medicine also contains:

  Lactose monohydrate, maize starch, macrogol 6000, talc, titanium dioxide E 171, magnesium stearate, polysorbate 80, hypromellose, sodium starch glycollate type A, polyacrylate dispersion 30%
- What does the medicine look like and what is the content of the package:
  - White sustained release tablet with a score line.
  - 30 tablets in each package.
- License holder and address: Medison Ltd. Hashiloach 10, POB 7090, Petach-Tiqva
- Manufacturer and address: Hennig Arzneimittel GmbH & Co. KG Liebigstr. 1-2
  65439 Flörsheim, Germany
- This leaflet was checked and approved by the Ministry of Health in: 06/13
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1108229409