Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Bezafibrate Medomie
Prolonged-release tablets

Active ingredient and its quantity
Each tablet contains bezafibrate 400 mg.

Inactive ingredients and allergens – see section 6 **'Additional information'**. See also **'Important information about some of this medicine's ingredients'** in section 2.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your 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 it seems to you that their illness is similar to yours.

1. What is this medicine intended for?
Bezafibrate Medomie is used to lower the level of triglycerides (lipids) in the blood alongside a suitable diet and non-medicinal treatments such as exercise and weight loss.

Therapeutic group:
Fibrates

2. Before using this medicine
Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (bezafibrate) or to any of the other ingredients this medicine contains (see section 6 '**Additional information**').
- You are sensitive (allergic) to fibrates or have developed a sensitivity to sunlight or artificial light (e.g. sunbeds) when using fibrates.
- you are taking medicines in the statin group (e.g. atorvastatin) and have any of the following conditions (see also, '**Special warnings regarding the use of this medicine**') which may increase the risk of your developing muscle disease (weakness, wasting of muscle tissue or muscle pain):
  - impaired kidney function
  - an underactive thyroid (hypothyroidism)
  - severe infection
  - trauma
  - surgery
  - changes in the levels of hormones or electrolytes in your body (seen in blood tests)
  - a high alcohol intake
- you are having dialysis
- you have liver disease
- you have gall bladder disease
- you have nephrotic syndrome (a kidney disorder)
- you have severely impaired kidney function

Special warnings about using this medicine

Before using Bezafibrate Medomie, tell your doctor if:

- you have an abnormal level of fats (lipids) in your blood caused by:
  - uncontrolled type 2 diabetes mellitus
  - an underactive thyroid (hypothyroidism)
  - nephrotic syndrome (a kidney disorder)
  - an abnormal protein level in the blood
  - obstructive liver disease
  - medication therapy
- you have an alcohol addiction
- you have any of the following conditions which may increase the risk of developing muscle disease (weakness, wasting of muscle tissue or muscle pain):
  - impaired kidney function
  - an underactive thyroid (hypothyroidism)
  - severe infection
  - trauma
  - surgery
  - changes in the levels of hormones or electrolytes in your body (seen in blood tests)
  - a high alcohol intake
  - are over 65 years old
  - have a family history of muscle disease

Children and adolescents
Bezafibrate Medomie is not intended for use in children. There is no information about the dosage regimen that is suitable for children and adolescents.

Tests and follow-up
If you have impaired kidney function, your doctor may refer you to have tests regularly.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. In particular, inform your doctor or pharmacist if you are taking:

- anti-coagulants in the coumarin group e.g. warfarin (used to prevent blood clotting).
- antidiabetic medicines such as insulin (used in diabetes).
- ciclosporin (used to suppress the immune system).
- anion exchange resins such as cholestyramine (used to lower cholesterol levels). When using Bezafibrate Medomie, they should not be taken within 2 hours of each other.
- statins e.g. atorvastatin (used to lower cholesterol levels). See also '**Do not use this medicine if**'.
- monoamine-oxidase inhibitors (MAOIs) e.g. phenelzine (used to treat depression).
- oestrogen or medicines which contain oestrogen.

Using this medicine and food
Take the tablet whole with a sufficient amount of water after a meal.

Using this medicine and alcohol consumption
Before taking the medicine, tell your doctor or pharmacist if you are addicted to alcohol or consume large amounts of alcohol (these conditions may increase the risk of development of muscle disease (weakness, muscle tissue wasting or muscle pain)). Do not use the medicine if

you are taking medicines in the statin group (e.g., atorvastatin) and consume large amounts of alcohol.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Fertility
There is insufficient information available on the effects of bezafibrate tablets on human fertility. Animal fertility studies with bezafibrate have not indicated reduced fertility.

Pregnancy
There is limited information on use of bezafibrate in pregnant women. Bezafibrate Medomie is not recommended for use during pregnancy and in women of childbearing potential not using contraception.

Breastfeeding
There is insufficient information available on the excretion of bezafibrate or its metabolites in human milk. A risk to the suckling child cannot be excluded. Consult your doctor on whether to discontinue breast-feeding or discontinue/abstain from Bezafibrate Medomie therapy, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Driving and using machines
Bezafibrate Medomie tablets may make you feel dizzy and can have a minor to moderate effect on the ability to drive or operate machinery. Make sure you do not feel dizzy before you drive or operate machinery.

Important information about some of this medicine's ingredients
Bezafibrate Medomie contains lactose (a type of sugar). If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to use this medicine?
Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The recommended dose is usually:

Adults:
One tablet after breakfast or dinner. Swallow the tablet whole with a sufficient amount of water.

Elderly:
Your doctor may reduce the dose by switching you to a medicine that is not as strong, depending on your kidney function.

Impaired kidney function:
If you have impaired kidney function, your doctor may prescribe you a medicine that is not as strong.

Do not exceed the recommended dose.

Bezafibrate Medomie tablets are film-coated prolonged-release tablets. Do not crush, split or chew the tablet.

Bezafibrate tablets and an anion exchange resin should not be taken within 2 hours of each other.

If you have accidentally taken a higher dose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Signs of an overdose include abnormal muscle breakdown (muscle pain, weakness or swelling) which can lead to kidney problems (rhabdomyolysis).

If you forget to take the medicine at the required time, do not take a double dose to make up for the forgotten one. If you forget to take the dose, take it as soon as you remember, and then take the next dose at the right time.

Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects</u>

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

<u>Contact your doctor immediately if you notice any of the following effects:</u>

- an allergic reaction (hypersensitivity) (uncommon): swelling of the face, lips, tongue or throat, narrowing of the airways causing difficulty breathing or swallowing, skin reactions such as pale or red irregular raised patches with severe itching, itching, sensitivity to sunlight or artificial light (e.g. sun 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): muscle pain or weakness, swelling.

<u>Common side effects (affect up to 1 in 10 users)</u>

- decreased appetite, stomach disorders

<u>Uncommon side effects (affect up to 1 in 100 users)</u>

dizziness, headache, bloated feeling, feeling sick, diarrhoea, stomach pain, constipation, indigestion, blocked bile flow (cholestasis), itching, pale or red irregular raised patches with severe itching (hives), rash, sensitivity to sunlight or artificial light (e.g. sun beds), hair loss (alopecia), muscle weakness, cramps or pain (myalgia), acute kidney failure, erection problems, changes in the levels of certain enzymes within the body (seen in a blood tests), increased blood levels of creatinine.

<u>Rare side effects (affect up to 1 in 1,000 users)</u>

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

Very rare side effects (affect up to 1 in 10,000 users)
Inflammation in the lungs (interstitial lung disease) causing shortness of breath (which may get worse over time) or cough (usually dry and non-productive). Blood and lymphatic disorders: Decreased levels of platelets in the blood causing a disorder characterised by blood spots, bruising and discolouring to the skin (thrombocytopenic purpura), decreased levels of haemoglobin levels (the red blood pigment), increased levels of certain enzymes within the body (seen in blood tests), serious skin reactions: circular, irregular red patches on the skin of the hands and arms (erythema multiforme), severe form of skin rash with 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), changes in the numbers and types of your blood cells. If you notice increased tendency towards bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion or abnormal paleness of the skin, you should tell your doctor who may instruct you to have a blood test.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.il.

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions
- Store below 30˚C.
- Protect from humidity.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Tablet core:
hypromellose (HMPC K100 LV), lactose monohydrate, povidone (K-30), magnesium stearate, colloidal anhydrous silica, sodium lauryl sulphate
Tablet coating:
purified talc, lactose monohydrate, titanium dioxide, hypromellose (HPMC E-5), macrogol (PEG 8000), polysorbate 80, sodium citrate, eudragit NE 30 D

What the medicine looks like and contents of the pack:
Bezafibrate Medomie tablets are white to off-white, round, biconvex, coated tablets, debossed "J9" on one side of the tablet and plain on the other side.

The medicine is marketed in a pack containing 30 prolonged-release tablets.

Registration holder's name and address
Medomie Pharma Ltd., 5358305 POB 816, Givatayim

Manufacturer's name and address
Medreich Limited (Unit 3)
survey No 4/3, Avalahalli, Anjanapura, Bangalore, Karnataka, India, 560062

Approved in June 2024.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
176-67-37749-99