

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Bezalip® Mono 400mg**  
(bezafibrate)

Your medicine is known as the above but will be referred to as Bezalip Mono throughout the remainder of this leaflet.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

- 1. What Bezalip Mono is and what it is used for**
- 2. What you need to know before you take Bezalip Mono**
- 3. How to take Bezalip Mono**
- 4. Possible side effects**
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**1. What Bezalip Mono is and what it is used for**

Bezalip Mono belongs to a group of medicines, commonly known as fibrates.

These medicines are used to lower the level of fats (lipids) in the blood. For example the fats known as triglycerides. Bezalip Mono is used, alongside a low fat diet and other non-medical treatments such as exercise and weight loss, to lower levels of fats in the blood.

**2. What you need to know before you take Bezalip Mono**

**Do not take Bezalip Mono:**

- if you are **allergic** (hypersensitive) to bezafibrate or any of the other ingredients in the tablets (see section 6).
- if you are **allergic** (hypersensitive) to fibrates or have developed a sensitivity to sunlight or artificial light (e.g. sunbeds) when taking these medicines.
- if you are taking **statins** (e.g. atorvastatin) **and** have any of the following which may increase the risk of you **developing muscle disease** (weakness, wasting and pain):
  - impaired **kidney** function
  - an underactive **thyroid** (hypothyroidism)
  - severe infection
  - **trauma**
  - **surgery**
  - a change in the levels of **hormones** or **chemicals** in your body (seen in a blood test)
  - a high **alcohol** intake.
- if you are having **dialysis**.
- if you have **liver** disease.
- if you have **gall bladder** disease.
- if you have **nephrotic syndrome** (a kidney disorder).
- if you have impaired **kidney** function.

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Bezalip Mono:

- 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 content in the blood
  - obstructive liver disease
  - medication
- if you have an **alcohol addiction**.

- if you have any of the following which may increase the risk of you **developing muscle disease** (weakness, wasting and pain):
  - impaired kidney function
  - an underactive thyroid (hypothyroidism)
  - severe infection
  - Trauma
  - Surgery
  - a change in the levels of hormones or chemicals in your body (seen in a blood test)
  - a high alcohol intake
  - are elderly (over 65 years old)
  - have a family history of muscle disease.

**Children and adolescents**

Bezalip Mono should not be used in children.

**Other medicines and Bezalip Mono**

**Tell your doctor or pharmacist** if you are taking, have recently taken or might take any other medicines. Especially:

- coumarin-type anti-coagulants 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 colestyramine (used to lower cholesterol). Bezalip Mono and an anion exchange resin should not be taken within 2 hours of each other.
- statins e.g. atorvastatin (used to lower cholesterol).
- monoamine-oxidase inhibitors (MAOIs) e.g. phenelzine (used in depression).
- oestrogen or medicines which contain oestrogen.

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**

Bezalip Mono may make you feel dizzy. Make sure you are not affected before you drive or operate machinery.

**Tests**

If you have impaired kidney function, your doctor may want to monitor you regularly by carrying out tests.

**Important information about some of the ingredients of Bezalip Mono**

This medicine contains lactose. If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

**3. How to take Bezalip Mono**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets **whole with water, after food in the morning or evening**.

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

**The recommended dose is:**

**Adults:** One tablet a day (400mg bezafibrate a day).

**Elderly:** Your doctor may reduce the dose depending on how well your kidneys are working.

**Children:** Not recommended.

**Impaired kidney function:** Do not take Bezalip Mono if you have impaired kidney function or are having dialysis.