PACKAGE LEAFLET: INFORMATION FOR THE USER

BEZALIP® RETARD TABLETS 400MG/ BEZALIP® MONO 400MG TABLETS

(bezafibrate)

Your medicine is available using the names Bezalip Retard Tablets 400mg or Bezalip Mono 400mg Tablets but will be referred to as Bezalip throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Index

1. What Bezalip is and what it is used for
2. Before you take
3. How to take
4. Possible side effects
5. How to store
6. Further information

1. What Bezalip is and what it is used for

Bezalip 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. Before you take

Do not take Bezalip and **tell** your doctor if you:

- are **allergic** (hypersensitive) to bezafibrate or any of the other ingredients in the tablets (see section 6).
- are **allergic** (hypersensitive) to fibrates or have developed a sensitivity to sunlight or artificial light (e.g. sunbeds) when taking these medicines.
- 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.
- are having **dialysis**.
- have **liver** disease.
- have **gall bladder** disease.
- have **nephrotic syndrome** (a kidney disorder).
- have impaired **kidney** function.

Check with your doctor or pharmacist before taking Bezalip 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.

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. 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 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 and breast-feeding

Speak to your doctor before taking Bezalip during pregnancy or breast-feeding.

Driving and using machines

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

Sugar intolerance

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.

Tests

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

3. How to take

Always take Bezalip exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

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

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

Doses:

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 if you have impaired kidney function or are having dialysis.

If you take more than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include abnormal muscle breakdown (muscle pain or weakness, swelling) which can lead to kidney problems (rhabdomyolysis).

If you forget to take the tablets

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

4. Possible side effects

Like all medicine, Bezalip can cause side effects, although not everybody gets them.

Contact your doctor immediately if you notice signs of:

- **an allergic reaction (hypersensitivity):** swelling of the face, lips, tongue or throat, itchy skin rash or narrowing of the airways causing difficulty breathing or swallowing.
- **gallstones:** pain in the upper abdomen or yellowing of the skin or whites of the eyes (jaundice).
- **abnormal muscle breakdown (rhabdomyolysis):** muscle pain or weakness, swelling.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- **Common** (occurs in less than 1 in 10 users): decreased appetite, stomach disorders.
- **Uncommon** (occurs in less than 1 in 100 users): 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 test), increased blood levels of creatinine.
- **Rare** (occurs in less than 1 in 1,000 users): damage to nerve endings causing tingling, pins and needles, inflammation of the pancreas (pancreatitis), depression, difficulty sleeping.

- **Very rare** (occurs in less than 1 in 10,000 users): inflammation in the lungs (interstitial lung disease), 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 the red blood pigment haemoglobin, increased levels of certain enzymes within the body (seen in a blood test), 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 bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion or abnormal paleness of the skin, you should tell your doctor who may want you to have a blood test.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store

- Do not store above 25°C.
- Store in a dry place.
- Keep out of the sight and reach of children.
- Do not use after the expiry date printed on the carton label or blister strip. The expiry date refers to the last date of that month.
- If your doctor tells you to stop taking the tablets, please take them back to the pharmacist for safe disposal. Only keep the tablets if your doctor tells you to.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will advise you what to do.
- Medicines must not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Bezalip contains
Each modified release tablet contains 400mg bezafibrate.

Bezalip also contain the following:
lactose monohydrate, polyvidone K25, sodium lauryl sulphate, hypromellose, magnesium stearate, macrogol 10000, Eudragit NE 30D, colloidal silicon dioxide, talc, titanium dioxide (E171), polysorbate 80 and sodium citrate.

What Bezalip looks like and contents of the pack
Bezalip are white, film-coated, modified release tablets coded 'D9' on one side and plain on the reverse.

Bezalip are available as blister packs of 30 tablets.

Manufacturer
This product is manufactured by: Cenexi SAS, France.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

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