Bezafibrate 200 mg Film-coated Tablets

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 Bezafibrate is and what it is used for

Bezafibrate 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. Bezafibrate 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 Bezafibrate

Do not take Bezafibrate:
- 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 severely impaired **kidney** function.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Bezafibrate:
- 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
Bezafibrate should not be used in children.

Other medicines and Bezafibrate
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). Bezafibrate 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
Bezafibrate 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.

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

3 How to take Bezafibrate

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.**

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

The recommended dose is:

Adults: One tablet three times a day (600mg bezafibrate a day). Each tablet should be swallowed whole with sufficient fluid after a meal.

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

Children: Not recommended.

Impaired kidney function: If you have impaired kidney function, your doctor may give you a different dose, especially if you are having dialysis.

If you take more Bezafibrate 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 Bezafibrate

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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

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

Contact your doctor immediately if you notice signs of:

- **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.
- **blood and lymphatic disorders (very rare):** 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), 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.
- **serious skin reactions (very rare):** 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).**

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

Common (may affect up to 1 in 10 people): decreased appetite, stomach disorders.

Uncommon (may affect up to 1 in 100 people): 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 (may affect up to 1 in 1000 people): damage to nerve endings causing tingling, pins and needles, inflammation of the pancreas (pancreatitis), depression, difficulty sleeping.

Very rare (may affect up to 1 in 10,000 people): inflammation in the lungs (interstitial lung disease) causing shortness of breath (which may get worse over time) or cough (usually dry and non-productive).

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 website at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to Store Bezafibrate

Keep out of the sight and reach of children.
Do not store above 25°C.
Do not use Bezafibrate after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Bezafibrate contains

- The active substance (the ingredient that makes the tablets work) is bezafibrate. Each tablet contains 200mg of the active substance.
- The other ingredients are:
  Tablet core: maize starch, microcrystalline cellulose, colloidal silicon dioxide, sodium starch glycollate, magnesium stearate.
  Film-coating: polyvinyl alcohol, titanium dioxide (E171), macrogol, talc.

What Bezafibrate looks like and contents of the pack

Bezafibrate tablets are white round film-coated tablets.

Pack size is 100.

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer

Cenexi,
52, Rue Marcel et Jacques Gaucher,
94120 Fontenay-Sous-Bois,
France.

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