PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

Sandoz® Bezafibrate 400 (film-coated tablets)

Bezafibrate

Contains sugar (lactose 62,00 mg per tablet)

Read all of this leaflet carefully before you start taking SANDOZ BEZAFIBRATE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- SANDOZ BEZAFIBRATE tablets have been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SANDOZ BEZAFIBRATE is and what it is used for
2. What you need to know before you take SANDOZ BEZAFIBRATE
3. How to take SANDOZ BEZAFIBRATE
4. Possible side effects
5. How to store SANDOZ BEZAFIBRATE
6. Contents of the pack and other information

1. What SANDOZ BEZAFIBRATE is and what it is used for

SANDOZ BEZAFIBRATE is used for the treatment of cholesterol, which have failed to respond adequately to diet and other behavioural changes, i.e. weight loss and physical activity. Bezafibrate is also used to treat cholesterol that persists, despite the appropriate treatment of the underlying disease (e.g. diabetes mellitus).

2. What you need to know before you take SANDOZ BEZAFIBRATE

Do not take SANDOZ BEZAFIBRATE:

- If you are hypersensitive (allergic) to bezafibrate, or any of the other ingredients of SANDOZ BEZAFIBRATE (listed in section 6).
- If you are pregnant, trying to become pregnant or breastfeeding your baby.
- If you have any kidney (renal) or liver disease.
- If you suffer from any hypoalbuminaemic states such as the nephrotic syndrome (kidney syndrome).
- If you are currently undergoing dialysis and have impaired renal function (serum creatinine > 135 µmol/L or creatinine clearance < 60 ml/min).
- If you have gall bladder disease with or without gall stones.
- If you are allergic to other fibrates or have developed a sensitivity to sunlight or artificial light (e.g. sunbeds) when taking these medicines.
- If you are also taking a statin (medicine to lower cholesterol e.g. atorvastatin) and have any of the conditions listed under ‘Warnings and precautions’, which may increase the risk of you developing muscle disease (weakness, wasting and pain known as myopathy).

Warnings and precautions

Take special care with SANDOZ BEZAFIBRATE:

SANDOZ BEZAFIBRATE should be used in addition to eating the correct diet, exercise, weight loss and the treatment of pre-existing problems of the metabolism in the body (e.g. diabetes, gout).

Tell your doctor if you are undergoing dialysis and have an impaired renal function. If your kidneys are mildly impaired, your kidney function should be tested regularly. If you have severe renal impairment or have a kidney condition called nephrotic syndrome (kidney syndrome), you should not take SANDOZ BEZAFIBRATE.

While taking this medication your liver function needs to be tested regularly.

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
- age over 65
- family history of muscle disorders
- suffered from muscle disease due to other blood lipid lowering medicines or fibrate

If you are having abdominal pain, fever, nausea, vomiting and tenderness of the abdomen with touching, you may have inflammation of the pancreas (pancreatitis). If you experience these symptoms, you should consult your doctor immediately.

If you are having abdominal bloating, intolerance of fatty foods, indigestion and wind after starting treatment with SANDOZ BEZAFIBRATE. These could be the symptoms of developing gallstone.

Secondary causes such as type 2 diabetes, kidney disease, an underactive thyroid (hypothyroidism), liver disease and alcoholism should be treated before starting bezafibrate.

Children and adolescents

SANDOZ BEZAFIBRATE is not recommended for use in children and adolescents.

Other medicines and SANDOZ BEZAFIBRATE

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor or pharmacist if you are currently using:

- HMG-CoA reductase inhibitors or statins (medicines used to reduce cholesterol e.g. atorvastatin). These increase the risk of serious myopathy (muscle disease).
- Oestrogens, which are hormones and are included in hormone replacement medicines and the oral contraceptive pill.
- Medicines used to suppress the immune system, usually taken following an organ transplant, such as ciclosporin.
- Cholestyramine, an interval of two hours should be maintained between taking the two medications.
- Blood thinning tablets e.g. warfarin.
- Anti-diabetic medicines like insulin and sulphonylureas (tolbutamide).
- Anti-depressants (selegiline, moclobemide).
- Phenytoin (anti-epileptic) and furosemide (water tablet).

SANDOZ BEZAFIBRATE with food, drink and alcohol

SANDOZ BEZAFIBRATE tablets should be taken with or after food and swallowed whole with a little water.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice, before taking this medicine.

You should not take SANDOZ BEZAFIBRATE while pregnant or breastfeeding.

Driving and using machines

SANDOZ BEZAFIBRATE can cause dizziness. If affected, you should not drive or use machines.

SANDOZ BEZAFIBRATE contains lactose

SANDOZ BEZAFIBRATE tablets contain an ingredient called lactose (milk sugar). If you have severe lactose intolerance, galactose intolerance, or glucose-galactose malabsorption, tell your doctor before taking SANDOZ BEZAFIBRATE tablets.

SANDOZ BEZAFIBRATE tablets may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take SANDOZ BEZAFIBRATE

Do not share medicines prescribed for you with any other person.

Always take SANDOZ BEZAFIBRATE exactly as your doctor has told you. Check with your doctor if you are not sure. If you have the impression that the effect of SANDOZ BEZAFIBRATE is too strong or too weak, talk to your doctor or pharmacist.

Diet is the basis of the treatment of all disorders of lipid metabolism and should be prescribed by a doctor. Obese patients should lose weight.

The standard dose of SANDOZ BEZAFIBRATE 400 mg daily is one tablet daily, after a meal either in the morning or evening.

The tablet should be swallowed whole with a liquid.

If you take more SANDOZ BEZAFIBRATE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take SANDOZ BEZAFIBRATE

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

If you stop taking SANDOZ BEZAFIBRATE

Do not stop or change your treatment before talking to your doctor.

4. Possible side effects

SANDOZ BEZAFIBRATE can have side effects. Not all side effects reported for SANDOZ BEZAFIBRATE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SANDOZ BEZAFIBRATE, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking SANDOZ BEZAFIBRATE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- An allergic reaction (hypersensitivity): any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching.
- 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.

- 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).

These are all very serious side effects. If you have them, you may have had a serious reaction to SANDOZ BEZAFIBRATE. You may need urgent medical attention or hospitalisation.

The following side effects can be experienced:

Frequent side effects:

- Loss of appetite.
- Stomach disorders.

Less frequent side effects:

- Co-existing abnormal reduction in the number of red and white blood cells, as well as platelets.
- Decreased levels of platelets in the blood causing a disorder characterised by blood spots, bruising and discolouring to the skin (thrombocytopenic purpura).
- Red blood cell deficiency.
- A reduction in the number of white blood cells, which may lead to more frequent infections.
- Mass gain.
- Depression.
- Difficulty getting to sleep.
- Headache.
- Dizziness, fatigue, drowsiness.
- Numbness or weakness of the arms and legs (peripheral neuropathy).
- Feeling of tingling, prickling, pins and needles or burning sensation.

- Inflammation in the lungs (interstitial lung disease) causing shortness of breath (which may get worse over time).
- Nausea, abdominal discomfort, diarrhoea, dyspepsia, flatulence, constipation.
- Inflammation of the pancreas (pancreatitis).
- Abnormal liver function test.
- Itching, pale or red irregular raised patches with severe itching (hives).
- Rash, sensitivity to sunlight or artificial light (e.g. sun beds).
- Skin rashes.
- Hair loss.
- Muscle pain and weakness.
- Muscle cramps.
- Acute kidney failure.
- Problems with getting or maintaining an erection (erectile dysfunction).
- Increased blood levels of creatinine, changes in levels of certain enzymes within the body, decreased levels of the red blood pigment haemoglobin and changes in the numbers and types of your blood cells (seen in a blood test).
- Irregular heart rate.

The frequency of the following side effects are unknown:

- Vomiting.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SANDOZ BEZAFIBRATE.

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store SANDOZ BEZAFIBRATE

- Store below 25 °C in a well closed container, protected from light.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use the tablets after the expiry date printed on the blisters and containers. Decomposed products may be toxic.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SANDOZ BEZAFIBRATE tablets contain

The active substance is bezafibrate.

The other ingredients are: Colloidal silicon dioxide (Aerosil 200), lactose, magnesium stearate, maize starch, opadry II white (OY-B-28920) (lecithin, polyvinyl alcohol, purified talc, titanium dioxide (CI 77891), xanthan gum), povidone K30 and purified talc.

What SANDOZ BEZAFIBRATE looks like and contents of the pack

White, round, biconvex, film coated tablets.

Amber glass bottles, blisters or white opaque securitainers of 30 or 100 tablets.

Not all packs may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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Jukskei View

Midrand

2090

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Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07