INFORMATION FOR THE CONSUMER

Full prescribing information is available to doctors and pharmacists on request.

Sandoz Fenofibrate E reduces levels of low density cholesterol (LDL-C or bad cholesterol), and other lipids called triglycerides (fatty substances found in the blood), while increasing levels of high density cholesterol (HDL-C or good cholesterol) in the blood.

Sandoz Fenofibrate E is used, in conjunction with the appropriate diet, in the treatment of adult patients with:

a. type 2 diabetes (non-insulin dependent), with dyslipoproteinemia (abnormal lipid levels in the blood, including high cholesterol), with or without elevated triglycerides, Fredrickson classification types IIa and IIb);

b. high serum triglyceride levels (Fredrickson classification types IV and V), who are at high risk for complications.

Sandoz Fenofibrate E may be taken with another medicine known as ezetimibe, in addition to diet and other lifestyle changes. Ezetimibe adds to the cholesterol-lowering effect of Sandoz Fenofibrate E. Ezetimibe works by decreasing the absorption of cholesterol in the small intestine. Sandoz Fenofibrate E lowers cholesterol in a different way; it works in the liver.

Sandoz Fenofibrate E is only available on prescription. This medicine should only be used to supplement an appropriate diet recommended and followed up by your doctor for the long-term treatment of raised lipid levels; prescription of this medicine in no way replaces dietary treatment. In addition, depending on the situation, your doctor may recommend further physical exercise, weight loss or other lifestyle measures.

Take exactly as instructed by your doctor. Do not change the dose without your doctor’s advice. Consult your doctor before stopping treatment.

DO NOT USE SANDOZ FENOFIBRATE E IF:

- you have liver or kidney problems;
- you have gallbladder problems;
- you have pancreatitis (an inflamed pancreas which causes abdominal pain);  
- you are allergic to fenofibrate or similar drug or if you are allergic to any of the ingredients in Sandoz Fenofibrate E tablets (see WHAT DOES SANDOZ FENOFIBRATE E CONTAIN?)
- you are pregnant think you may be pregnant or are planning to have a baby; in the event of pregnancy during treatment, your doctor should be informed and Sandoz Fenofibrate E should be discontinued;
- you are breast-feeding or planning to breast-feed your baby.
• you have a photoallergy (skin sensitivity to sunlight or UV light) when taking a fibrate (a class of drugs used for lowering cholesterol, which includes Sandoz Fenofibrate E and gemfibrozil) or an anti-inflammatory drug called ketoprofen.
• you are taking statins and have muscle problems or have potential risks of developing muscle problems.
• you are under 18 years of age.

BEFORE STARTING TREATMENT WITH THIS MEDICINE, your doctor must know:

• if you have had an allergic reaction to (or poorly tolerated) Sandoz Fenofibrate E, any of its ingredients (see WHAT DOES SANDOZ FENOFIBRATE E CONTAIN?), or any other lipid treatment;
• if you suffer from liver or kidney problems;
• if you have an inflamed liver (hepatitis) - signs include yellowing of the skin and the whites of the eyes (jaundice) and an increase in liver enzymes (shown in blood tests);
• if you have pancreas problems;
• if you have a gallbladder or gallstone problem;
• if you have an under-active thyroid gland (hypo-thyroidism);
• if you are pregnant, or intend to become pregnant, or are breast-feeding, or intend to breast-feed;
• if you are taking any other medicine, prescription or non-prescription. Of particular concern are:
  o Statins (a class of drugs, which includes atorvastatin, pravastatin, simvastatin, etc., used to lower cholesterol). Taking a statin at the same time as Sandoz Fenofibrate E may increase the risk of muscle problems.
  o Oral anticoagulants (blood thinning agents, such as warfarin)
  o Cyclosporine (a drug which may be taken following an organ transplant)
  o Cholestyramine or similar drug (another type of cholesterol lowering agent)
  o Estrogens (hormones which may be found in oral contraceptives or hormone replacement therapy)
  o a particular class of medicines to treat diabetes (such as rosiglitazone or pioglitazone)

Your doctor will ask you to have regular medical check-ups and appropriate laboratory tests. It is important to respect the dates proposed for these tests: we strongly recommend that you keep these appointments faithfully so that any abnormalities that may occur can be identified promptly. These problems can include muscle inflammation and breakdown, which can cause kidney damage or even death. The risk of muscle breakdown is higher in some patients. Tell your doctor if:
• you are over 70 years old;
• you have kidney problems;
• you have thyroid problems;
• you or a close family member has muscle problem which runs in the family;
• you drink large amounts of alcohol;
• you are taking medicines called statins to lower cholesterol such as simvastatin, atorvastatin, pravastatin, rosuvastatin or fluvastatin;
• you have ever had muscle problems during treatment with fibrates such as fenofibrate, bezafibrate or gemfibrozil.

PROPER USE OF THE MEDICINE:

• Sandoz Fenofibrate E may be taken once daily, anytime, with or without food.
• The recommended dose of Sandoz Fenofibrate E is one 145 mg tablet daily.
• In elderly patients and those with mild to moderate kidney disease, the doctor may initiate treatment with one 48 mg tablet daily, taken anytime, with or without food. The doctor may later decide to increase this dose.
• Never change the dose unless directed by your doctor.
• Sandoz Fenofibrate E is not recommended for use in children.
• The safety of using Sandoz Fenofibrate E in combination with a statin has not been extensively studied in patients. Therefore, the combined use of fenofibrate with a statin should be avoided unless recommended by your doctor.
• Another type of cholesterol lowering agent called ezetimibe can also be taken with Sandoz Fenofibrate E.
• Tell your doctor about any health problem that occurs while you are taking Sandoz Fenofibrate E. If you need other medical treatment while taking Sandoz Fenofibrate E, let your doctor know that you are taking Sandoz Fenofibrate E.
• If you forget a dose, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

STORAGE AND STABILITY

Store between 15°C and 30°C.

OVERDOSAGE

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS

In addition to its intended action, any medicine may cause side effects.

Tell your doctor if you feel in any way unwell while taking Sandoz Fenofibrate E.

Some common side effects may include abdominal pain, constipation, diarrhea, flatulence, nausea, vomiting, headache, dizziness, skin reactions, fatigue and raised levels of liver enzymes in the blood. This is not a complete list of side effects. If you experience any unexpected
symptoms while taking Sandoz Fenofibrate E, contact your doctor or pharmacist.

Stop taking Sandoz Fenofibrate E and see a doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

- allergic reaction - the signs may include swelling of the face, lips, tongue or throat, which may cause difficulty in breathing
- stomach pain - this may be a sign that your pancreas is inflamed (pancreatitis)
- chest pain and feeling breathless - these may be signs of a blood clot in the lung (pulmonary embolism)
- pain, redness or swelling in the legs - these may be signs of a blood clot in the leg (deep vein thrombosis)
- yellowing of the skin and whites of the eyes (jaundice), or an increase in liver enzymes - these may be signs of an inflamed liver (hepatitis).

Muscle pain or cramps, or muscle weakness, may indicate rare, but more serious, side effects. If you suffer any unexplained muscle pain, stop the drug and contact your doctor immediately.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.
WHAT DOES SANDOZ FENOFIBRATE E CONTAIN?

Sandoz Fenofibrate E 145 mg and 48 mg tablets contain, in addition to fenofibrate, the following nonmedicinal ingredients: croscarmellose sodium, hypromellose, lactose anhydrous, magnesium stearate, simethicone emulsion and sodium lauryl sulphate.

Ingredients of the simethicone emulsion: benzoic acid, glycerides, methyl cellulose, polyethylene glycol sorbitan tristearate, polyethylene glycol stearate, simethicone, sorbic acid, sulfuric acid and xanthan gum.

THIS MEDICINE IS PRESCRIBED FOR A PARTICULAR HEALTH PROBLEM AND FOR YOUR PERSONAL USE. DO NOT GIVE IT TO OTHER PERSONS. KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

IF YOU WANT FURTHER INFORMATION, ASK YOUR DOCTOR OR PHARMACIST.

This leaflet was prepared by Sandoz Canada Inc.

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