

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

^{Pr} **APO-FENO-SUPER**
fenofibrate, microcoated formulation tablets

Read this carefully before you start taking **APO-FENO-SUPER** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **APO-FENO-SUPER**.

What is APO-FENO-SUPER used for?

APO-FENO-SUPER is used in adults, including adults with type 2 diabetes, to lower cholesterol and blood fat levels. APO-FENO-SUPER is to be used together with dietary and lifestyle changes.

How does APO-FENO-SUPER work?

APO-FENO-SUPER lowers cholesterol by reducing the amount of bad cholesterol (LDL) and fatty substances in the blood (triglycerides). It also increases the amount of good cholesterol (HDL) in the blood.

What are the ingredients in APO-FENO-SUPER?

Medicinal ingredient: fenofibrate

Non-medicinal ingredients: Croscarmellose sodium, hydroxypropylcellulose Type LF, hydroxypropyl methylcellulose 2910 E5, polyethylene glycol 8000, titanium dioxide and purified water.

APO-FENO-SUPER comes in the following dosage form:

Film-coated tablet: 100 mg, 160 mg and 200 mg

Do not use APO-FENO-SUPER if you:

- have serious liver or kidney problems;
- have gallbladder problems;
- have pancreatitis (an inflamed pancreas which causes abdominal pain);
- are allergic (hypersensitive) to fenofibrate or similar drugs or if you are allergic to any of the ingredients in APO-FENO-SUPER;
- are allergic (hypersensitive) to peanuts, arachis oil, soya lecithin, lactose or related products due to risk of allergic reaction;
- are pregnant, think you may be pregnant or are planning to get pregnant. If you get pregnant while taking APO-FENO-SUPER, contact your healthcare professional immediately.
- are breast-feeding or planning to breast-feed;
- have a photoallergy (skin sensitivity to sunlight or UV light) when taking a fibrate (a class of drugs used for lowering cholesterol, which includes APO-FENO-SUPER and gemfibrozol) or an anti-inflammatory drug called ketoprofen;

- are taking statins (another type of drug used to lower cholesterol) and have muscle problems or have potential risks of developing muscle problems;
- are under 18 years of age.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take APO-FENO-SUPER. Talk about any health conditions or problems you may have, including if you:

- have liver or kidney problems;
- have pancreas problems;
- have gallstones;
- have thyroid problems;

Other warnings you should know about:

You should have regular check-ups with your healthcare professional while taking APO-FENO-SUPER. Your healthcare professional will also do regular blood work to make sure you are responding well to APO-FENO-SUPER and that you are not experiencing side effects. These side effects can include serious muscle problems, which can cause kidney damage or even death. The risk of muscle problems is higher in some patients.

Tell your healthcare professional if you:

- are over 70 years old;
- have kidney or liver problems;
- have thyroid problems;
- or a close family member has muscle problems which run in the family;
- drink large amounts of alcohol;
- have a serious infection or have recently had surgery or suffered a trauma;
- are dehydrated or suffer from excessive vomiting, diarrhea, or sweating;
- are taking drugs called statins to lower cholesterol such as simvastatin, atorvastatin, pravastatin, rosuvastatin or fluvastatin;
- have ever had muscle problems during treatment with fibrates such as fenofibrate, bezafibrate or gemfibrozil.

While taking APO-FENO-SUPER if you experience muscle pain, tenderness or weakness, especially with a fever, contact your healthcare professional immediately.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with APO-FENO-SUPER:

- Statins (other drugs used to lower cholesterol) such as atorvastatin, pravastatin, simvastatin, etc. Taking a statin at the same time as APO-FENO-SUPER may increase the risk of serious muscle problems.
- Ezetimibe (used to lower cholesterol);
- Blood thinners, such as warfarin;
- Cyclosporine (a drug which may be taken following an organ transplant);
- Cholestyramine or similar drugs (used to lower cholesterol);

- Estrogens (hormones which may be found in birth control pills or hormone replacement therapy);
- Some drugs used to treat diabetes, such as rosiglitazone or pioglitazone.

How to take APO-FENO-SUPER:

- APO-FENO-SUPER should be taken with food.
- Swallow the tablet whole with a glass of water.
- Do not crush or chew the tablet.

Usual adult dose:

The recommended dose of APO-FENO-SUPER is one 160 mg tablet daily.

Overdose:

If you think you have taken too much APO-FENO-SUPER, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

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.

What are possible side effects from using APO-FENO-SUPER

These are not all the possible side effects you may feel when taking APO-FENO-SUPER. If you experience any side effects not listed here, contact your health care professional.

Side effects may include:

- Stomach pain, constipation, diarrhea, gas
- Nausea, vomiting
- Headache
- Dizziness
- Fatigue
- Trouble sleeping
- Low sex drive
- Skin rashes, redness and itching, sensitivity of the skin to light
- Hair loss
- Weight loss
- Joint pain

APO-FENO-SUPER can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	

UNCOMMON Allergic reaction: swelling of the face, lips, tongue or throat, which may cause difficulty in breathing			✓
Blood clot in the lung: sudden chest pain and trouble breathing			✓
Blood clot in the leg: pain, redness or swelling in the legs			✓
Inflammation of the pancreas: stomach pain that lasts and gets worse when you lie down, nausea, vomiting			✓
RARE Serious muscle problems: muscle pain or cramps, or muscle weakness, especially together with fever and generally feeling unwell			✓
Liver problems: yellowing of the skin and whites of the eyes, dark urine			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects.

The Canada Vigilance Program does not provide medical advice.

Storage:

Store at 15°C to 30°C. Protect from moisture and light.

Keep out of reach and sight of children.

If you want more information about APO-FENO-SUPER:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website (<http://www.apotex.ca/products>), or by calling 1-844-596-9526

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