

# EP-FENO TABLET 145 mg

Fenofibrate 145mg

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## What EP-Feno is used for

EP-Feno 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.

EP-Feno can be used in addition to other medicines (statins) in some circumstances when levels of fats in the blood are not controlled with a statin alone .

## How EP-Feno works

EP-Feno 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.

## Before you use EP-Feno

### When you must not use it

Do not take EP-Feno if:

- you are allergic to fenofibrate or any of the other ingredients of this medicine
- while taking other medicines, you have had an allergic reaction or skin damage from sunlight or UV light (those medicines include other fibrates and an anti-inflammatory medicine called 'ketoprofen')
- you have severe liver, kidney or gallbladder problems
- you have pancreatitis (an inflamed pancreas which causes abdominal pain)

which is not caused by high levels of fat in the blood

Do not take EP-Feno if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking EP-Feno.

### Before you start to use it

Talk to your doctor or pharmacist or nurse before taking EP-Feno if:

- you have any liver or kidney problems
- you may have an inflamed liver (hepatitis) - signs include yellowing of the skin and the whites of the eyes (jaundice), an increase in liver enzymes (shown in blood tests), stomach pain and itching
- you have an under-active thyroid gland (hypothyroidism)

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking EP-Feno.

### Taking other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines. In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- anti-coagulants to thin your blood (such as warfarin)
- other medicines to control fat levels in the blood (such as, statins or fibrates). Taking a statin at the same time as EP-Feno may increase the risk of muscle problems
- a particular class of medicines to treat diabetes (such as rosiglitazone or pioglitazone)
- ciclosporin (an immunosuppressant)

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking EP-Feno.

## How to use EP-Feno

### How much to use

#### **In adults and elderly patients:**

The recommended dosage is one tablet a day

#### **In patients with renal impairment (kidney problems):**

A reduced dose is recommended. A lower dose of fenofibrate should be used.

#### **In patient with hepatic impairment (liver problems):**

EP-Feno is not recommended since not enough data are available

#### **In younger patients and infants:**

EP-Feno is not recommended in children and adolescent less than 18 years old since not enough data are available

### When to use it

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 tablet with a glass of water.
- Do not crush or chew the tablet.
- The tablet can be eaten at any time with or without food

### How long to use it

Do not stop taking EP-Feno unless your doctor tells you to, or the tablets make you feel unwell. This is because abnormal levels of fats in the blood need treating for a long period of time. Remember that as well as taking EP-Feno it is also important that you:

- have a low fat diet
- take regular exercise.

If your doctor stops your medicine, do not keep any leftover tablets unless your doctor tells you to. If you have any further questions on the use of this

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medicine, ask your doctor or pharmacist or nurse.

### **If you forget to take it**

- If you forget a dose, take as soon as you remember, if it is still early
- Then take your next tablet at the normal time.
- Do not take a double dose to make up for a forgotten dose. If you are worried about this talk to your doctor.

### **If you take too much (overdose)**

If you take more EP-Feno than you should or if someone else has taken your medicine, tell your doctor or contact your nearest hospital.

### **While you are using EP-Feno**

#### **Things you must do**

Stop taking EP-Feno and see a doctor straight away if you get unexplained cramps or painful, tender or weak muscles while taking this medicine.

- This is because this medicine may cause muscle problems, which may be serious.
- These problems are rare but include muscle inflammation and breakdown. This can cause kidney damage or even death.

Your doctor may do a blood test to check your muscles before and after starting treatment.

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 problems 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 statins or fibrates such as fenofibrate, bezafibrate or gemfibrozil.

If any of the above apply to you (or you are not sure), talk to your doctor before taking EP-Feno.

### **Things you must not do**

#### **Pregnancy, breast-feeding and fertility**

Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. As there is not enough experience with the use of EP-Feno during pregnancy, you should use EP-Feno only, if your doctor considers it absolutely necessary.

It is not known, whether the active substance in EP-Feno passes into breast-milk. Therefore, you should not use EP-Feno if you are breastfeeding or planning to breast-feed your baby.

Ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines** This medicine will not affect you being able to drive or use tools or machines.

### **Things to be careful of**

EP-Feno contains lactose (types of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars (have intolerance to some sugars), talk to your doctor before taking this medicine.

### **Side effects**

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

Stop taking EP-Feno 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
- cramps or painful, tender or weak muscles - these may be signs of muscle inflammation or breakdown, which can cause kidney damage or even death
- 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).

Stop taking EP-Feno and see a doctor straight away, if you notice any of the side effects above.

Other side effects include:

Common (affects less than 1 in 10 people):

- diarrhoea
- stomach pain
- wind (flatulence)
- feeling sick (nausea)
- being sick (vomiting)
- raised levels of liver enzymes in the blood – shown in tests.

Uncommon (affects less than 1 in 100 people):

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- headache
- gallstones
- skin rash, itchy skin
- sexual dysfunction
- increase in creatinine (produced by the kidneys) – shown in tests
- pancreatitis (inflammation of the pancreas leading to abdominal pain)
- thromboembolism: pulmonary embolism (blood clot in the lung causing chest pain and breathlessness), deep vein thrombosis (blood clot in the leg causing pain, redness or swelling)
- muscle pain, muscle inflammation, muscle cramps and weakness.

Rare (affects less than 1 in 1,000 people):

- hair loss
- feeling dizzy (vertigo)
- feeling exhausted (fatigue)
- increase in urea (produced by the kidneys) – shown in tests
- increased sensitivity of your skin to sunlight, sun lamps and sunbeds
- drop in haemoglobin (that carries oxygen in blood) and white blood cells – shown in tests
- hepatitis (inflammation of the liver), symptoms of which may be mild jaundice (yellowing of the skin and whites of the eyes), stomach pain and itching
- hypersensitivity (allergic reaction).

Side effect that are not known:

- severe form of skin rash with reddening, peeling and swelling of the skin that resembles severe burns
- long-term lung problems
- muscle breakdown
- complications of gallbladder stones.

- If you get any unusual breathing discomfort, tell your doctor straight away.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## **Storage and Disposal of EP-Feno** **Storage**

Keep this medicine out of the sight and reach of children. Keep this medicine in the original package in order to protect from moisture.

Store below 30°C. Protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

## **Disposal**

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.

## **Product Description**

### **What it looks like**

White to off-white biconvex oblong tablet, 15.5 x 8.5 mm, embossed “F” on one side and “145” on the other side.

3x10’s

### **Ingredients**

The active substance is Fenofibrate 145mg.

The other ingredients are Hypromellose, Sodium laurilsulfate, Simethicone

emulsion 30%, Lactose anhydrous, Croscarmellose sodium, Magnesium stearate.

### **MAL Number**

MALxxxxxxxxAZ

### **Manufacturer and Product Registration Holder**

#### **Manufacturer**

ETHYPHARM

Chemin De La Poudriere, Le Grand Quevilly, 76120, France

#### **Product Registration Holder**

GIRAFFES ENTERPRISE SDN. BHD.

C18-3A, 3 TWO SQUARE, JALAN 19/1, 46300, PETALING JAYA, SELANGOR

### **Date of Revision**

5-Feb-2026

### **Serial Number**

NPRA (R2) 25/039