

Lipimac 145mg Film Coated Tablets

Fenofibrate 145mg

What is in this leaflet?

1. What Lipimac 145 are used for
2. How Lipimac 145 works
3. Before you use Lipimac 145
4. How to use Lipimac 145
5. While you are using Lipimac 145
6. Side effects
7. Storage and Disposal of Lipimac 145
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

1. WHAT LIPIMAC 145 ARE USED FOR:

Lipimac 145 are used, alongside a low fat diet and other nonmedical treatments such as exercise and weight loss, to lower levels of fats in the blood. Lipimac 145 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.

2. HOW LIPIMAC 145 WORKS:

Lipimac 145 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.

3. BEFORE YOU USE LIPIMAC 145:

When you must not use it

Do not take Lipimac 145 if:

- You are allergic to Fenofibrate or any of the other ingredients of this medicine.
- You are allergic (hypersensitive) to peanut or arachis oil or soya lecithin or related products.
- 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 Lipimac 145 if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Lipimac 145.

Before you start to use it

Talk to your doctor or pharmacist or nurse before taking Lipimac 145 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 Lipimac 145.

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 Lipimac 145 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 Lipimac 145.

4. HOW TO USE LIPIMAC 145:

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):

Lipimac 145 Tablets is not recommended since not enough data are available.

In younger patients and infants:

Lipimac 145 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 Lipimac 145 Tablets 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 Lipimac 145 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 medicine, ask your doctor or pharmacist or nurse.

If you forget to use Lipimac 145

- 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 use Lipimac 145 too much

(Overdose):

If you take more Lipimac 145 than you should or if someone else has taken your medicine, tell your doctor or contact your nearest hospital.

5. WHILE YOU ARE USING LIPIMAC 145:

- Things you must do

Stop taking Lipimac 145 and see a doctor straight away if you get unexplained cramps or painful, tender or weak muscles while taking this medicine.

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Fenofibrate 145mg

- 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 Lipimac 145.

- 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 Lipimac 145 during pregnancy, you should use Lipimac 145 only, if your doctor considers it absolutely necessary. It is not known, whether the active substance in Lipimac 145 passes into breast-milk.

Therefore, you should not use Lipimac 145 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

Lipimac 145 contains lactose and sucrose (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.

Lipimac 145 contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

6. SIDE EFFECTS

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

Stop taking Lipimac 145 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 Lipimac 145 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):

- Diarrhea
- 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):

- 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 have been reported by patients, but where the chance of it happening is 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.

Lipimac 145mg Film Coated Tablets

Fenofibrate 145mg

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my (Consumer → Reporting → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)).

7. STORAGE AND DISPOSAL OF LIPIMAC 145:

- Storage

Keep out of reach of children.

Store below 30°C.

Store in the original packaging to 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.

8. PRODUCT DESCRIPTION

- What it looks like and contents of the pack

White coloured, biconvex, oval shaped, film coated tablets debossed with "C49" on one side and plain surface on other side.

Alu-Clear PVC/PVDC blister pack of 10 Tablets.

- What Lipimac 145 Tablets contains

The active substance is Fenofibrate 145mg.

The other ingredients are:

Hypromellose, Sodium lauryl sulphate, Lecithin, Purified water, Sucrose, Lactose Monohydrate, Silicified microcrystalline Cellulose, Crospovidone, Colloidal silicon dioxide, Sodium stearyl fumarate.

Coating: Polyvinyl Alcohol, Talc, Titanium Dioxide, Lecithin, Xanthan Gum & Purified water.

- MAL Number:

MAL24096049AZ

9. MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Manufacturer:

Macleods Pharmaceuticals Limited,
Block N-2, Village Theda, Post Office
Lodhimajra, Tehsil Baddi, District Solan,
Himachal Pradesh-174101, India.

Product Registration Holder:

Macleods Pharmaceutical Sdn. Bhd.,
A2-27-1 Soho Suites KLCC, Jalan Perak,
50450 Kuala Lumpur, Malaysia.

10. Date of revision

15/10/2024

11. Serial Number

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