

Package leaflet: Information for the user

Thylip 200 mg hard capsules

fenofibrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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

1. What [Invented name] is and what it is used for

[Invented name] 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'.

[Invented name] 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.

[Invented name] can be used in addition to other medicines (called 'statins') in some circumstances when levels of fats in the blood are not adequately controlled with a statin alone.

2. What you need to know before you take [Invented name]

Do not take [Invented name] if you:

- are allergic to fenofibrate or any of the other ingredients of this medicine (listed in section 6),
- are having or have had an allergic reaction or skin damage from sunlight or UV light while concomitantly taking other medicines (other fibrates and an anti-inflammatory medicine called 'ketoprofen'),
- have severe liver, kidney or gallbladder problems,
- have pancreatitis (an inflamed pancreas which causes abdominal pain), which is not caused by high levels of fat in the blood.

Do not take [Invented name] if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking [Invented name].

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking [Invented name] if you:

- have any liver or kidney problems,
- may 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),
- have an underactive thyroid gland (hypothyroidism).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking [Invented name].

Effects on muscles

Stop taking [Invented name] 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 be life threatening.

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,
- have kidney problems,
- have thyroid problems,
- drink large amounts of alcohol,
- or a close family member has a muscle problem which runs in the family,
- are taking medicines called statins to lower cholesterol, such as simvastatin, atorvastatin, pravastatin, rosuvastatin or fluvastatin,
- 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 [Invented name].

Other medicines and [Invented name]

Tell your doctor or pharmacist 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 with [Invented name] may increase the risk of muscle problems,
- Certain types of medicines to treat diabetes (such as rosiglitazone or pioglitazone),
- Cyclosporin to suppress your immune system.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking [Invented name].

[Invented name] with food and drink

It is important to take the capsule with food - it will not work as well if your stomach is empty.

Pregnancy and breast-feeding

- Do not take [Invented name], and tell your doctor if you are pregnant, think you might be pregnant or are planning to have a baby.
- Do not take [Invented name] if you are breast-feeding or planning to breast-feed your baby.

Driving and using machines

This medicine does not affect your ability to drive or use tools or machines.

[Invented name] contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

[Invented name] contains sodium benzoate

This medicine contains not more than 8.3 micrograms sodium benzoate (E211) in each capsule.

[Invented name] contains parabens

This medicine contains parabens called methyl para-hydroxybenzoate (E218) and propyl para-hydroxybenzoate, which may cause allergic reactions (possibly delayed).

[Invented name] contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per capsule, that is to say essentially 'sodium-free'.

3. How to take [Invented name]

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will determine the appropriate strength for you, depending on your condition, your current treatment and your personal risk status.

Taking this medicine

- Swallow the capsule whole with a glass of water.
- Do not open or chew the capsule.
- Take the capsule with food - it will not work as well if your stomach is empty

Remember that as well as taking [Invented name] it is also important that you:

- Have a low-fat diet,
- Take regular exercise.

How much to take

The recommended dose is 1 capsule (200 mg) daily.

People with kidney problems

If you have kidney problems, your doctor may tell you to take a lower dose. Ask your doctor or pharmacist about this.

Use in children and adolescents

The use of [Invented name] is not recommended in children and adolescents under the age of 18 years.

If you take more [Invented name] than you should

If you have taken more [Invented name] than you should, or if children have been taking medicine by accident, please contact your doctor or nearest hospital.

If you forget to take [Invented name]

- take the next dose with your next meal.
- on the following day, take your dose 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 stop taking [Invented name]

Do not stop taking [Invented name] unless your doctor tells you to, or the capsules make you feel unwell. This is because abnormal levels of fats in the blood need treating for a long period of time.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Stop taking [Invented name] and contact a doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

Uncommon (may affect up to 1 in 100 people):

- 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).

Rare (may affect up to 1 in 1,000 people):

- Allergic reaction – the signs may include swelling of the face, lips, tongue or throat, which may cause difficulty in breathing
- 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).

Not known: frequency cannot be estimated from the available data

- Serious form of skin rash with reddening, peeling and swelling of the skin that resembles severe burns
- Long-term lung problems. If you get any unusual breathing discomfort, contact your doctor straight away
- Cramps or painful, tender or weak muscles – these may be signs of rhabdomyolysis, muscle inflammation or breakdown, which can cause kidney damage or even death.

Stop taking [Invented name] and contact a doctor straight away, if you notice any of the side effects above.

Other side effects include

Common (may affect up to 1 in 10 people):

- Diarrhoea, stomach pain, wind (flatulence), feeling sick (nausea), being sick (vomiting)
- Elevated levels of liver enzymes in the blood - shown in tests
- Elevated levels of homocysteine (too much of this amino acid in the blood has been associated to a higher risk of coronary heart disease, stroke and peripheral vascular disease, although a causal link has not been established).

Uncommon (may affect up to 1 in 100 people):

- Headache
- Gallstones
- Reduced sex drive
- Rash, itching or red patches on the skin
- Muscle pain, muscle inflammation, muscle cramps and weakness
- Increase in creatinine (produced by the kidneys) – shown in tests.

Rare (may affect up to 1 in 1,000 people):

- Hair loss
- Increase in urea (produced by the kidneys) – shown in tests
- Increased sensitivity of your skin to sunlight, sun lamps and sunbeds
- Reduced levels of haemoglobin (that carries oxygen in the blood) and reduced number of white blood cells – shown in tests.

Not known (frequency cannot be estimated from the available data):

- Feeling exhausted (fatigue).

If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in](#)

[Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

Keep this medicine out of the sight and reach of children.
This medicine does not require any special storage conditions.

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

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 protect the environment.

6. Contents of the pack and other information

What [Invented name] contains

- The active substance is fenofibrate. Each capsule contains 200 mg of fenofibrate.
- Other ingredients are
 - *Capsule content*: sugar spheres, hypromellose, sodium laurilsulfate, dimeticone, octoxinol, polysorbate 20, propylene glycol (E1520), sodium benzoate (E211), methyl para-hydroxybenzoate (E218), propyl para-hydroxybenzoate, simeticone, cetostearyl alcohol, cetostearyl alcohol ethoxylate and talc.
 - *Capsule shell*: gelatine, sodium laurilsulfate, titanium dioxide (E171) and iron oxide yellow (E172).

What [Invented name] looks like and contents of the pack

[Invented name] are hard gelatine capsules having yellow cap and clear transparent body filled with white to off-white spherical pellets, packed in clear transparent PVC-Aluminium blister.

[Invented name] are available in blister packs of 100 capsules.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised 2023-12-15

Detailed information on this medicine is available on the website of (name of MA Agency (link)).