

CHOLIB 145MG/20MG FILM COATED TABLET

Fenofibrate 145mg/ Simvastatin 20mg

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1. What CHOLIB is used for

Cholib contains two different active substances: fenofibrate (belongs to the group called 'fibrates') and simvastatin (belongs to the group called 'statins'). They are both used to lower levels of total cholesterol, "bad" cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, they both raise levels of "good" cholesterol (HDL cholesterol).

2. How CHOLIB works

Cholib is used in adults at high risk of problems like heart attack and stroke who have high blood levels of 2 types of fats (triglycerides and LDL cholesterol). It is given to lower triglycerides and increase the good cholesterol (HDL cholesterol) in patients whose bad cholesterol (LDL cholesterol) is already controlled with simvastatin alone in a dose of 20 mg.

3. Before you use CHOLIB

- When you must not use it

Do not take Cholib:

- If you are allergic to fenofibrate or simvastatin or any of the other ingredients of Cholib (listed in section 8).

- If you are allergic to peanut, arachis oil, soya lecithin or related substances.
- If while taking other medicines, you have had an allergic reaction or skin damage from sunlight or UV light (these medicines include other fibrates and an anti-inflammatory medicine called "ketoprofen").
- If you have liver or gallbladder problems.
- If you have pancreatitis (inflamed pancreas which causes abdominal pain), which is not caused by high levels of fats in the blood.
- If you have moderate or severe kidney problems.
- If you have a history of muscle problems during treatment to lower the level of fats in the blood with either of the active substances in this medicine, or with other statins (such as atorvastatin, pravastatin or rosuvastatin) or fibrates (such as bezafibrate or gemfibrozil).
- If you are already taking the following medicines:
 - danazol (a man-made hormone used to treat endometriosis).
 - ciclosporin (a medicine often used in organ transplant patients).
 - itraconazole, ketoconazole, fluconazole or posaconazole (medicines for fungal infections)
 - HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (medicines used for HIV infection and AIDS).
 - glecaprevir/ pibrentasvir (a medicine used to treat hepatitis C virus)
 - erythromycin, clarithromycin, or telithromycin (medicines for bacterial infections)
 - nefazodone (a medicine for depression).
- If you are already being treated and will continue your treatment with:
 - a fibrate (e.g. gemfibrozil)
 - a statin (medicines to lower the levels of fats in the blood, e.g. simvastatin, atorvastatin).
 - medicinal products containing cobicistat
- If you are under 18 years of age.
- If you are pregnant or breast-feeding.

Do not take Cholib if any of the above applies to you. Check with your doctor or pharmacist if you are not sure.

Before you start to use it Talk to your doctor or pharmacist before taking Cholib if:

- you have an underactive thyroid gland (hypothyroidism)
- you are due to have an operation. You may need to stop taking Cholib for a short time
- you drink large amounts of alcohol (more than 21 units (210 mL) a week of pure alcohol)
- you have chest pain and are feeling breathless. These may be signs of a blood clot in the lung (pulmonary embolism)
- you have severe lung disease
- you have kidney disease.
- you or a close family member have a muscle problem which runs in the family

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- you are taking or, in the last 7 days, have taken or been given a medicine called fusidic acid (a medicine for bacterial infection)

If any of the above applies to you, talk to your doctor or pharmacist before taking Cholib. Check with your doctor or pharmacist if you are not sure.

Also tell your doctor or pharmacist if you have muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

Your doctor should do a blood test before you start taking Cholib. This is to check how well your liver is working.

Taking other medicines
It is particularly important to tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This also concerns medicines obtained without a prescription including herbal medicines. Tell your doctor or pharmacist if you are taking any of the following medicines:

- danazol (a man-made hormone used to treat endometriosis)
- ciclosporin (a medicine often used in organ transplant patients)
- itraconazole, ketoconazole, fluconazole or posaconazole (medicines for fungal infections)
- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (medicines used for HIV infection and AIDS)
- glecaprevir/ pibrentasvir (a medicine used to treat hepatitis C virus)
- products that are inhibitors of Breast Cancer Resistant

- Protein (e.g., elbasvir and grazoprevir)
- erythromycin, clarithromycin, or telithromycin (medicines for bacterial infections)
- nefazodone (a medicine for depression)
- a fibrate (e.g. fenofibrate, gemfibrozil)
- a statin (e.g. simvastatin, atorvastatin)

Do not take Cholib if any of the above applies to you. Check with your doctor or pharmacist if you are not sure.

In particular tell your doctor or pharmacist if you are taking any of the following medicines (taking Cholib with any of these medicines can increase the risk of muscle problems):

- high doses of at least 1 gram per day of niacin (nicotinic acid) or a treatment containing niacin (medicine for lowering fat levels in the blood)
- colchicine (a medicine used to treat gout)

Do not take fusidic acid (a medicine for bacterial infections) while using this medicine.

As well as the medicines listed previously, tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines:

- anticoagulants such as warfarin, fluindione, phenprocoumon or acenocoumarol (medicines to prevent blood clots)
- pioglitazone (a particular class of medicines to treat diabetes)
- rifampicin (a medicine used to treat tuberculosis)

If any of the above applies to you, talk to your doctor or pharmacist before taking Cholib. Check with your doctor or pharmacist if you are not sure.

4. How to use CHOLIB

- How much to use

Your doctor will determine the appropriate strength for you, depending on your condition, your current treatment and your personal risk status. The usual dose is one tablet per day.

- When to use it

You can take Cholib with or without food.

Swallow the tablet with a glass of water.

Do not crush or chew the tablet.

You should continue a low-fat diet or other measures (e.g. exercise, weight reduction) whilst taking Cholib.

- How long 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.

- If you forget to take it

Do not take a double dose to make up for a forgotten tablet. Take the next tablet at your regular time on the next day. If you are worried about this, talk to your doctor or pharmacist. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you take too much (overdose)

If you have taken more Cholib than you should or if someone else has taken your medicine, tell your doctor or pharmacist or contact your nearest hospital.

5. While you are using CHOLIB

- Things you must do

Your doctor may also want you to have blood tests to check how well your liver is working after you start taking Cholib.

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While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

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

Children and adolescents

Cholib must not be given to children and adolescents (age below 18 years).

- *Things you must not do*

Pregnancy and breast-feeding

- Do not take Cholib if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking Cholib, stop taking it immediately and contact your doctor.
- Do not take Cholib if you are breast-feeding or plan to breast-feed your baby, because it is not known if the medicine passes into breast milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Cholib is not expected to affect you being able to drive or use tools or machines. However, it should be taken into account that some people get dizzy after taking Cholib.

- *Things to be careful of*

Cholib with food and drink

Grapefruit juice contains one or more components that alter how the body uses Cholib. Do not consume grapefruit juice with Cholib as it may increase your risk of muscle problems.

Important information about some of the ingredients of Cholib

Cholib contains types of sugars called lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Cholib contains soya lecithin. If you are allergic to peanut, soya or arachis oil do not use Cholib.

Cholib contains sunset yellow FCF (E110) that may cause allergic reactions.

6. Side effects

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

- Unexplained muscle pain, tenderness, or weakness may be sign of muscle break down. Therefore please contact your doctor immediately if you experience these symptoms. This is because on rare occasions, there have been cases of serious muscle problems including muscle breakdown resulting in kidney damage; and very rare deaths have occurred. Compared to a fibrate or a statin alone, the risk of muscle breakdown is increased when you take these 2 medicines together, as in Cholib. It is higher in female patients or in patients 65 years or older.

Some patients have experienced the following serious side effects whilst taking fenofibrate or simvastatin (both active substances in Cholib):

- allergic reaction - the signs may include swelling of the face, lips, tongue or throat, which may cause difficulty in breathing
- Hypersensitivity reaction to Cholib with symptoms like:

pain or inflammation of the joints, inflammation of blood vessels, unusual bruising, skin eruptions and swelling, hives, skin sensitivity to the sun, fever, flushing, shortness of breath and feeling unwell, lupus-like disease picture (including rash, joint disorders, and effects on white blood cells)

- 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 and hepatic failure)
- increased sensitivity of your skin to sunlight, sun lamps and sunbeds

If any of the previously listed serious side effects happen, stop taking Cholib and tell your doctor immediately or go to the emergency room at your nearest hospital - you may need urgent medical treatment.

Some patients have experienced the following side effects whilst taking Cholib, fenofibrate or simvastatin:

Very common side effects (may affect more than 1 in 10 people):

- Increase in the blood level of "creatinine" (substance excreted by the kidneys)

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- Increase in blood levels of “homocysteine” (too much of this amino acid in the blood is related to a higher risk of coronary heart disease, stroke and peripheral vascular disease, although a causal link has not been established)

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

- increase in blood platelets count
- elevations in blood tests of liver function (transaminases)
- digestive disturbances (stomach pain, nausea, vomiting, diarrhoea and flatulence)
- infection of the upper respiratory tract

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

- muscle problems
- gallstones
- rashes, itching, red patches on the skin
- headache
- sexual difficulties

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

- low red blood cell count (anaemia)
- numbness or weakness of the arms and legs
- confusion
- feeling dizzy
- feeling exhausted (asthenia)
- increase in “urea” - produced by the kidneys - shown in tests
- increase in “gamma-glutamyltransferase” - produced by the liver - shown in tests
- increase in “alkaline phosphatase” - produced by the bile system - shown in tests
- increase in “creatine phosphokinase” - produced

by the muscle - shown in tests

- drop in haemoglobin (that carries oxygen in blood) and white blood cells- shown in tests
- trouble sleeping
- poor memory or memory loss
- hair loss
- constipation
- dyspepsia
- vision blurred
- visual impairment

Very rare side effects (may affect less than 1 in 10000 people):

- Muscle rupture
- Lichenoid drug eruptions
- Gynecomastia

The following side effects have also been reported but the frequency cannot be estimated from the available information (frequency not known):

- severe allergic skin rash with blisters
- complications of gall stones such as colic because of stones in bile duct, infection of the bile ducts or gall bladder
- diabetes mellitus
- erectile dysfunction
- feeling depressed
- sleep disturbances including nightmares
- specific lung disease with difficulties breathing (called interstitial lung disease)
- muscle weakness that is constant
- increase in “glycosylated haemoglobin” and blood glucose levels - markers for blood glucose control in diabetes mellitus - shown in tests
- myasthenia gravis (a disease causing general muscle weakness including weakness of the respiratory muscles in some cases). Ocular myasthenia (a disease

causing eye muscle weakness)

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 [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and Disposal of CHOLIB

- Storage

Keep this medicine out of the sight and reach of children. Do not use Cholib 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. Store below 30°C.

- 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 protect the environment

8. Product Description

- What it looks like

The film-coated tablet (tablet) is a, oval, biconvex, tan coloured 19.3 x 9.3 mm tablet with bevelled edges and the inscription 145/20 on one side. The tablets are provided in carton boxes with blisters containing 10, 30 or 90 tablets.

Not all pack sizes may be marketed.

- Ingredients

The active substances are fenofibrate and simvastatin. Each tablet contains 145 mg of fenofibrate and 20 mg of simvastatin.

The other ingredients are:

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Tablet core:

Butylhydroxyanisole (E320),
lactose monohydrate, sodium
laurilsulfate, starch,
pregelatinised (maize),
docusate sodium, sucrose,
citric acid monohydrate
(E330), hypromellose (E464),
crospovidone (E1202),
magnesium stearate (E572),
silicified microcrystalline
cellulose (comprised of
cellulose, microcrystalline and
silica, colloidal anhydrous),
ascorbic acid (E300).

Film-coat:

Poly (vinyl alcohol), partially
hydrolysed (E1203), titanium
dioxide (E171), talc (E553b),
lecithin (derived from soya
bean (E322)), xanthan gum
(E415), iron oxide red (E172),
iron oxide yellow (E172),
sunset yellow FCF (E110).

- *MAL Number:*
MAL17107003ACRZ

9. Manufacturer and Product Registration Holder

- *Manufacturer*
Fournier Laboratories Ireland
Ltd.,Angrove, Carrigtwohill, Co.
Cork, Ireland

Packed and released by:

Mylan Laboratories SAS, Lieu-
dit Maillard Route de Belleville
01400 Châtillon sur Chalaronne,
France

- *Product Registration Holder*
Abbott Laboratories (M) Sdn.
Bhd.

27-02, Level 27, IMAZIUM,
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Selangor Malaysia

10. Date of Revision

14/03/2024

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