

VYTOCOR 10MG/40MG TABLET

Ezetimibe/Simvastatin 10mg/40mg

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What VYTOCOR is used for

VYTOCOR is a medicine used to lower levels of total cholesterol, LDL (bad) cholesterol, and fatty substances called triglycerides in the blood. In addition, VYTOCOR raises levels of HDL (good) cholesterol. VYTOCOR is for patients who cannot control their cholesterol levels by diet alone. You should stay on a cholesterol-lowering diet while taking this medicine.

If you have heart disease, VYTOCOR reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalization for chest pain

How VYTOCOR works

VYTOCOR works to reduce your cholesterol in two ways. It reduces the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself. VYTOCOR does not help you lose weight.

Before you use VYTOCOR

- When you must not use it

Do not use it if you:

- are hypersensitive (allergic) to ezetimibe, simvastatin, or any of the other ingredients of VYTOCOR tablets
- have active liver disease

- are pregnant or breast-feeding
- are taking any of the following medicines:
 - certain antifungal medicines (such as itraconazole, ketoconazole, posaconazole, or voriconazole)
 - HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir)
 - hepatitis C antiviral agents (such as boceprevir, telaprevir, elbasvir, or grazoprevir)
 - certain antibiotics (such as erythromycin, clarithromycin, or telithromycin)
 - the antidepressant nefazodone
 - medicines containing cobicistat (used as an enhancer for antiretroviral agents)
 - gemfibrozil (a fibric acid medicine for lowering cholesterol)
 - cyclosporine (used as an immunosuppressant medicine to prevent organ transplant rejection)
 - danazol (used in treatment of endometriosis, fibrocystic breast disease and angioedema)

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

- Before you start use it

Tell your doctor about:

Pregnancy: Do not use VYTOCOR if you are pregnant, trying to become pregnant or suspect that you are pregnant. If you become pregnant while taking VYTOCOR, stop taking it and contact your physician immediately.

Breast-feeding: Do not use VYTOCOR if you are breast-feeding.

Medical Problems or Allergies:

Talk about any medical problems (including liver disease or liver problems) or allergies you have now or have had in the past. Tell your doctor if you consume substantial quantities of alcohol or have a past history of liver disease.

- Taking other medicines

Because taking VYTOCOR with any of the following medicines or substances can increase the risk of muscle problems (**see Side effects**), it is particularly important to tell your doctor if you are taking any of the following medicines or any of the medicines listed in the section "When you must not use it":

- amiodarone (a medicine used to treat an irregular heartbeat)
- verapamil, diltiazem, or amlodipine (medicine used to treat high blood pressure, angina, or other heart conditions)
- lomitapide (a medicine used to treat a serious and rare genetic cholesterol condition)
- daptomycin (a drug used to treat complicated skin and skin structure infections and bacteremia)
- grapefruit juice (which should be avoided while taking VYTOCOR).

It is also important to tell your doctor if you are taking anticoagulants (medicines that prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol), colchicine (a medication used for gout), niacin, or fenofibrate, another fibric acid derivative.

You should always tell your doctor about all medicines that you are taking or plan to take, including those obtained without a prescription. You should also tell any doctor who is prescribing a new medication for you that you are taking VYTOCOR.

How to use VYTOCOR

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

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- Take one tablet of VYTOCOR 10/40, orally each day. Your doctor will prescribe the suitable dose for you.
- Because of the increased risk of muscle problems, the VYTOCOR 10/80 tablet is only for patients at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.
- No special precautions for use in elderly

- When to use it

Use as directed by your doctor or pharmacist.

If your doctor has prescribed VYTOCOR along with cholestyramine (a bile acid sequestrant) or any other bile acid sequestrant, VYTOCOR should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.

Take VYTOCOR as a single daily dose in the evening, with or without food.

- How long to use it

Continue taking VYTOCOR for as long as your doctor recommends. VYTOCOR should be taken as directed by your health care provider. Continue taking your other cholesterol lowering medicines unless your doctor tells you to stop.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking VYTOCOR.

Tell your doctor immediately if you become pregnant while taking this medication.

It is important to have your cholesterol measured regularly, even if you are taking medication to treat high cholesterol. You should also know your cholesterol levels and goals.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give VYTOCOR to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Contact your physician promptly if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death.

- The risk of muscle breakdown is greater at higher doses of VYTOCOR, particularly the 10/80 mg dose.
- The risk of muscle breakdown is also greater for older patients (65

years of age and older), female patients, patients with kidney problems, and patients with thyroid problems.

Do not drive or operate machinery until you know how VYTOCOR affects you.

Side effects

Like all medicines, VYTOCOR can cause side effects, although not everybody gets them. If you experience any of the following serious side effects, stop taking your tablets and tell your doctor immediately or go to the nearest hospital's accident and emergency department.

The following common side effects were reported: muscle aches, elevations in blood tests of liver function; elevations in blood uric acid; elevations in the time it takes or blood to clot; protein in urine; weight decreased; dizziness; headache; tingling sensation; abdominal pain; indigestion; flatulence; nausea; vomiting; abdominal bloating; diarrhea; dry mouth; heartburn; rash; itching; hives; joint pain; muscle pain, tenderness, weakness or spasms; neck pain; pain in arms and legs; back pain; unusual tiredness or weakness; feeling tired; chest pain; swelling, especially in the hands and feet; sleep disorder; trouble sleeping.

Additionally, the following side effects have been reported in general use with either VYTOCOR, ezetimibe or simvastatin tablets (tablets that contain the active ingredients of VYTOCOR):

- allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing (which may require treatment right away), rash, and hives; raised red rash, sometimes with

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target-shaped lesions; muscle pain, tenderness, or weakness (that in very rare cases may not go away after stopping VYTOCOR); alterations in some laboratory blood tests; liver problems (sometimes serious); inflammation of the pancreas; constipation; depression; gallstones; inflammation of the gallbladder; poor memory; memory loss; confusion; erectile dysfunction; breathing problems including persistent cough and/or shortness of breath or fever. If you have muscle problems that do not go away even after your doctor has told you to stop taking VYTOCOR, please refer to your doctor.

If you are prescribed Vytocor, your healthcare professional may want to conduct routine blood tests to check your liver function before and after starting treatment and if you have any symptoms of liver problems while you take Vytocor. Call your doctor right away if you have the following symptoms of liver problems:

- feel tired or weak
- loss of appetite
- upper belly pain
- dark urine
- yellowing of your skin or the whites of your eyes

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

Storage and Disposal of VYTOCOR

- Storage

Store below 30°C.

Keep out of the reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

Product Description

- What it looks like

VYTOCOR 10/40mg: White to off-white, capsule shaped, with '40' marking on one side and '10' on the other side

- Ingredients

- Active ingredient(s)

VYTOCOR 10/40mg: Each tablet contains 10mg of Ezetimibe and 40mg of simvastatin

- Inactive ingredients

- Butylated Hydroxyanisole
- Propyl Gallate
- Citric acid
- Lactose Monohydrate
- Microcrystalline cellulose
- Hydroxypropyl methylcellulose
- Croscarmellose sodium
- Magnesium stearate

- MAL number:

VYTOCOR 10/40mg:
MALXXXXXXXXXXAZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn.Bhd.

Lot 2 & 4,
Jalan P/7, Section 13, Bangi
Industrial Estate,
43650 Bandar Baru Bangi,
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Product Registration Holder

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07/04/2020

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