

## Package leaflet: Information for the patient

# Zemil 10 mg tablets

## Ezetimibe

**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.

- 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

### What is in this leaflet

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

#### 1. What Zemil is and what it is used for

Zemil is a medicine to lower increased levels of cholesterol. It lowers levels of total cholesterol, "bad" cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, Zemil raises levels of "good" cholesterol (HDL cholesterol).

This medicine contains the active substance ezetimibe that works by reducing the cholesterol absorbed in your digestive tract.

Zemil adds to the cholesterol-lowering effect of statins, a group of medicines that reduces the cholesterol your body makes by itself.

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol.

LDL cholesterol is often called "bad" cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke. HDL cholesterol is often called "good" cholesterol because it helps keep the "bad" cholesterol from building up in the arteries and protects against heart disease.

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

Zemil is used for patients who cannot control their cholesterol levels by cholesterol lowering diet alone.

You should stay on a cholesterol-lowering diet while taking this medicine.

Zemil is used in addition to your cholesterol lowering diet if you have:

- A raised cholesterol level in your blood (primary hypercholesterolemia: heterozygous familial and non-familial).

- Together with a statin, when your cholesterol level is not well controlled with a statin alone.
- Alone, when statin treatment is inappropriate or is not tolerated.

- A hereditary illness (homozygous familial hypercholesterolemia) that increases the cholesterol level in your blood. You will also be prescribed a statin and may also receive other treatments.

- A hereditary illness (homozygous sitosterolemia, also known as phytosterolemia) that increases the levels of plant sterols in your blood.

If you have heart disease, Zemil combined with cholesterol-lowering medicines called statins reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalisation for chest pain.

Zemil does not help you lose weight.

#### 2. What you need to know before you take Zemil

If you use Zemil together with a statin, please read the package leaflet of that particular medicine.

#### Do not take Zemil:

- If you are allergic (hypersensitive) to ezetimibe or to any of the ingredients of this medicine (listed in section 6).

#### Do not take Zemil together with a statin:

- If you currently have liver problems.

- If you are pregnant or breast-feeding.

#### Warnings and precautions:

Talk to your doctor or pharmacist before taking Zemil.

Tell your doctor about all your medical conditions including allergies.

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

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

If you have moderate or severe liver problems, this medicine is not recommended.

The safety and efficacy of the combined use of Zemil and fibrates (medicines for lowering cholesterol) has not been established.

#### Children and adolescents:

Do not give this medicine to children and adolescents (6 to 17 years of age) unless prescribed by a specialist because there are limited data on safety and efficacy. Do not give this medicine to children less than 6 years old because there is no information in this age group.

#### Other medicines and Zemil:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor if you are taking any of the following:

- Ciclosporin (a medicine often used in organ transplant patients).

- Medicines to prevent blood clots, such as warfarin, phenprocoumon, acenocoumarol or fluiudione (anticoagulants).

- Cholestyramine (a medicine for lowering cholesterol), because it affects the way this medicine works.

- Fibrates (medicines for lowering cholesterol).

#### Zemil with food and drinks:

This medicine can be taken with or without food.

#### Pregnancy and breast-feeding:

Do not take this medication with a statin if you are pregnant, are trying to get pregnant or think you may be pregnant.

If you get pregnant while taking this medication with a statin, stop taking both medicines immediately and tell your doctor. There is no experience from the use of ezetimibe without a statin during pregnancy.

Ask your doctor for advice before using this medication if you are pregnant.

Do not take this medication with a statin if you are breast-feeding, because it is not known if the medicines are passed into breast milk.

Zemil without a statin should not be used if you are breast-feeding. Ask your doctor for advice.

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

#### Driving and using machines:

Zemil is not expected to interfere with your ability to drive or to use machinery. However, it should be taken into account that some people may get dizzy after taking this medicine.

#### Zemil contains Lactose

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

#### 3. How to take Zemil

Always take this medicine exactly as your doctor has told you. Continue taking your other cholesterol-lowering medicines unless your doctor tells you to stop. Check with your doctor or pharmacist if you are not sure.

#### Taking this medicine:

- Before starting Zemil, you should be on a diet to lower your cholesterol.

- You should keep on this cholesterol lowering diet whilst taking Zemil.

The recommended dose is one Zemil 10 mg tablet by mouth once a day.

You can take your medicine at any time of the day. You can take it with or without food.

If your doctor has prescribed Zemil along with a statin, both medicines can be taken at the same time. In this case, please read the dosage instructions in the package leaflet of that particular medicine.

If your doctor has prescribed this medicine along with cholestyramine or any other bile acid sequestrant (medicines for lowering cholesterol), you should take Zemil at least 2 hours before or 4 hours after taking the bile acid sequestrant.

#### If you take more Zemil than you should

Call your doctor or pharmacist immediately.

#### If you forget to take Zemil

Do not take a double dose to make up for a forgotten tablet, just take your normal amount of Zemil at the usual time the next day.

#### If you stop taking Zemil

Talk to your doctor or pharmacist because your cholesterol may rise again.

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

#### 4. Possible side effects

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

**Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems, including muscle breakdown resulting in kidney damage, can be serious and may become a potentially life-threatening condition.**

Allergic reactions, including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing (which requires treatment right away) have been reported in general use.

When used alone, the following side effects were reported:

- Common (may affect up to 1 of 10 patients):

abdominal pain; diarrhea; flatulence; feeling tired.

- Uncommon (may affect up to 1 of 100 patients):

elevations in some laboratory blood tests of liver (transaminases) or muscle (CK) function; cough; indigestion; heartburn; nausea; joint pain; muscle spasms; neck pain; decreased appetite; pain; chest pain; hot flush; high blood pressure.

Additionally, when used with a statin, the following side effects may occur:

- Common: elevations in some laboratory blood tests of liver function (transaminases); headache; muscle pain; tenderness or weakness.

- Uncommon: tingling sensation; dry mouth; itching; rash; hives; back pain; muscle weakness, pain in arms and legs; unusual tiredness or weakness; swelling, especially in the hands and feet.

When used with fenofibrate abdominal pain may occur.

Additionally, the following side effects may occur in general use:

Dizziness; muscle aches; liver problems; allergic reactions including rash and hives; raised red rash, sometimes with target-shaped lesions (erythema multiforme); muscle pain, tenderness or weakness; muscle breakdown; gallstones or inflammation of the gallbladder (which may cause abdominal pain, nausea, vomiting); inflammation of the pancreas often with severe abdominal pain; constipation; reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopenia); tingling sensation; depression; unusual tiredness or weakness; shortness of breath.

#### 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.

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Zemil

- Keep this medicine out of the sight and reach of children.

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

- Do not store above 30° C. Keep away from humidity.

- Do not use this medicine if you notice visible signs of deterioration.

- Do not throw away any medicines via wastewater.

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 Zemil contains

- The active substance is ezetimibe.

Each tablet contains 10 mg of ezetimibe.

- The other ingredients are croscarmellose sodium, povidone, lactose, microcrystalline cellulose, sodium lauryl sulphate and magnesium stearate.

##### What Zemil looks like and contents of the pack

White round tablets.

Zemil is available in boxes containing 30 tablets.

##### Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. – Lebanon

P.O. Box 90201 Jdeidet-El-Metn, Lebanon

Contact us: pharmaline@maliagroup.com

Website:www.pharmaline.com.lb

Reg. N° for Zemil, Lebanon: 24932/07

#### This is a medicament:

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

**Council of Arab Health Ministers  
Union of Arab Pharmacists**

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