

PACKAGE LEAFLET: INFORMATION FOR THE USER

ZOCOR® 10, 20, 40, 80 mg Film-coated Tablets

Simvastatin

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What ZOCOR is and what it is used for
2. Before you take ZOCOR
3. How to take ZOCOR
4. Possible side effects
5. How to store ZOCOR
6. Further information

1. WHAT ZOCOR IS AND WHAT IT IS USED FOR

ZOCOR is a medicine used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, ZOCOR raises levels of “good” cholesterol (HDL cholesterol). You should stay on a cholesterol-lowering diet while taking this medicine. ZOCOR is a member of the class of drugs called statins.

ZOCOR is used along with diet if you have:

- a raised cholesterol level in your blood (primary hypercholesterolaemia) or elevated fat levels in your blood (mixed hyperlipidaemia)
- a hereditary illness (homozygous familial hypercholesterolaemia) that increases the cholesterol level in your blood. You may also receive other treatments.
- coronary heart disease (CHD) or are at high risk of CHD (because you have diabetes, history of stroke, or other blood vessel disease). ZOCOR may prolong your life by reducing the risk of heart disease problems, regardless of the amount of cholesterol in your blood.

In most people, there are no immediate symptoms of high cholesterol. Your doctor can measure your cholesterol with a simple blood test. Visit your doctor regularly, keep track of your cholesterol, and discuss your goals with your doctor.

2. BEFORE YOU TAKE ZOCOR

Do not take ZOCOR

- if you are allergic (hypersensitive) to simvastatin or any of the other ingredients of ZOCOR Tablets (see Section 6: Further Information).
- if you currently have liver problems
- if you are pregnant or breast-feeding
- if you are taking one or more of the following drugs at the same time:

- itraconazole, ketoconazole, or posaconazole (medicines for fungal infections)
- erythromycin, clarithromycin, or telithromycin (antibiotics for infections)
- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (HIV protease inhibitors are used for HIV infections)
- nefazodone (a medicine for depression).

Take special care with ZOCOR

- Tell your doctor about all your medical conditions including allergies.
- Tell your doctor if you drink large amounts of alcohol.
- Tell your doctor if you have ever had liver disease. ZOCOR may not be right for you.
- Tell your doctor if you are due to have an operation. You may need to stop taking ZOCOR tablets for a short time.
- Your doctor should do a blood test before you start taking ZOCOR. 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 ZOCOR.
- Tell your doctor if you have severe lung disease.

Contact your doctor immediately 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; and very rare deaths have occurred.

The risk of muscle breakdown is greater at higher doses of ZOCOR and is greater in certain patients. Talk with your doctor if any of the following applies:

- you consume large amounts of alcohol
- you have kidney problems
- you have thyroid problems
- you are 65 years or older
- you are female
- you have ever had muscle problems during treatment with cholesterol-lowering medicines called “statins” or fibrates
- you or a close family member have a hereditary muscle disorder.

Using other medicines

It is particularly important to tell your doctor if you are taking any of the following drugs. Taking ZOCOR with any of these drugs can increase the risk of muscle problems (some of these have already been listed in the above section “Do not take ZOCOR”).

- ciclosporin (a medicine often used in organ transplant patients)
- danazol (a man-made hormone used to treat endometriosis)
- medicines like itraconazole, ketoconazole, floconazole, or posaconazole (medicines for fungal infections)
- fibrates like gemfibrozil and bezafibrate (medicines for lowering cholesterol)
- erythromycin, clarithromycin, telithromycin, or fusidic acid (medicines for bacterial infections)
- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (medicines for AIDS)
- nefazodone (a medicine for depression)
- amiodarone (a medicine for an irregular heartbeat)
- verapamil, diltiazem or amlodipine (medicines for high blood pressure, chest pain associated with heart disease, or other heart conditions)
- colchicine (a medicine used to treat gout).

As well as the medicines listed above, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription. In particular, tell your doctor if you are taking any of the following:

- medicines to prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol (anticoagulants)
- fenofibrate (another medicine for lowering cholesterol)
- niacin (another medicine for lowering cholesterol)
- rifamapicin (a medicine used to treat tuberculosis).

Also tell your doctor if you are taking niacin (nicotinic acid) or a niacin-containing product and are Chinese.

Taking ZOCOR with food and drink

Grapefruit juice contains one or more components that alter how the body uses some medicinal products, including ZOCOR. Consuming grapefruit juice should be avoided.

Pregnancy and Breast-feeding

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

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

Children

Safety and effectiveness have been studied in 10-17 year old boys and in girls who had started their menstrual period at least one year before (see HOW TO TAKE ZOCOR). ZOCOR has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Driving and using machines

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

Important information about some of the ingredients of ZOCOR

ZOCOR tablets contain a sugar called 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 ZOCOR

Always take ZOCOR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

The dose is 1 ZOCOR 10 mg, 20 mg, 40 mg, or 80 mg tablet by mouth once a day.

For children (10-17 years old), the recommended usual starting dose is 10 mg a day in the evening. The maximum recommended dose is 40 mg a day.

The 80 mg dose is only recommended for adult patients with very high cholesterol levels and at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.

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

Take ZOCOR in the evening. You can take it with or without food. The usual starting dose is 10, 20 or, in some cases, 40 mg a day. Your doctor may adjust your dose after at least 4 weeks to a maximum of 80 mg a day. Do not take more than 80 mg a day. Your doctor may prescribe lower doses, particularly if you are taking certain medicinal products listed above or have certain kidney conditions. Keep taking ZOCOR unless your doctor tells you to stop.

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

If you take more ZOCOR than you should

- please contact your doctor or pharmacist.

If you forget to take ZOCOR

- do not take an extra dose, just take your normal amount of ZOCOR at the usual time the next day.

If you stop taking ZOCOR

- your cholesterol may rise again.

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

4. POSSIBLE SIDE EFFECTS

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

The following terms are used to describe how often side effects have been reported:

- Rare (occurring in 1 or more of 10,000 and less than 1 of 1000 patients treated)
- Very rare (occurring in less than 1 of 10,000 patients treated).
- Frequency not known

The following rare serious side effects were reported.

If any of these serious side effects happen, stop taking the medicine and tell your doctor immediately or go to the emergency room at your nearest hospital.

- muscle pain, tenderness, weakness, or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.
- hypersensitivity (allergic) reactions including:
 - swelling of the face, tongue and throat which may cause difficulty in breathing
 - severe muscle pain usually in the shoulders and hips
 - rash with weakness of limbs and neck muscles
 - pain or inflammation of the joints
 - inflammation of the 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 blood cells)
- inflammation of the liver with yellowing of the skin and eyes, itching, dark-coloured urine or pale-coloured stool, liver failure (very rare)
- inflammation of the pancreas often with severe abdominal pain.

The following side effects have also been reported rarely:

- low red blood cell count (anaemia)
- numbness or weakness of the arms and legs
- headache, tingling sensation, dizziness
- digestive disturbances (abdominal pain, constipation, flatulence, indigestion, diarrhoea, nausea, vomiting)
- rash, itching, hair loss
- weakness
- trouble sleeping (very rare)
- poor memory (very rare).

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

- erectile dysfunction
- depression
- inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or fever.

Additional possible side effects reported with some statins:

- sleep disturbances, including nightmares
- memory loss
- sexual difficulties

Laboratory Values

Elevations in some laboratory blood tests of liver function and a muscle enzyme (creatin kinase) have been observed.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ZOCOR

Keep out of the reach and sight of children.

Do not use ZOCOR after the expiry date which is stated on the container.

Do not store above 25°C. Keep the blister in outer carton in order to protect from moisture.

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.

6. FURTHER INFORMATION

What ZOCOR contains

The active substance is simvastatin (10 mg, 20 mg, 40 mg, or 80 mg).

The other ingredients are: butylated hydroxyanisole (E320), ascorbic acid (E300), citric acid monohydrate (E330), microcrystalline cellulose (E460), pregelatinized starch, magnesium stearate (E572), and lactose monohydrate. The tablet coating contains hypromellose (E464), hydroxypropylcellulose (E463), titanium dioxide (E171), and talc (E553b). The 10 mg and 20 mg tablets also contain yellow ferric oxide (E172) and red ferric oxide (E172). The 40 mg and 80 mg tablets also contain red ferric oxide.

What ZOCOR looks like and contents of the pack

Zocor 10mg are peach-coloured, oval-shaped tablets marked 'MSD 735'

Zocor 20mg are tan-coloured, oval-shaped tablets marked 'MSD 740'

Zocor 40mg are brick-red coloured, oval-shaped tablets marked 'MSD 749'

Zocor 80mg are brick-red coloured, capsule-shaped tablets marked '543' on one side and '80' on the other.

Zocor Tablets are available in packs containing 28 tablets, 4 tablets or one tablet.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

The Marketing Authorisation Holder in the UK and Malta is Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, UK. The Marketing Authorisation Holder in Ireland is Merck Sharp & Dohme Ireland (Human Health) Ltd, Pelham House, South County Business Park, Leopardstown, Dublin 18, Ireland.

The Manufacturer of the 10mg, and 20mg tablets is Merck Manufacturing Division, Merck Sharp & Dohme Limited, Shotton Lane, Cramlington, Northumberland NE23 3JU, UK.

The manufacturer of the 40 mg and 80mg tablets is Merck Sharp & Dohme BV, Waarderweg 39, 2031 BN, Haarlem, The Netherlands.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria ZOCORD

Belgium ZOCOR

Denmark ZOCOR

Finland ZOCOR

France ZOCOR

Germany ZOCOR 5 mg Filmtabletten; ZOCOR 10 mg Filmtabletten; ZOCOR 20 mg Filmtabletten; ZOCOR FORTE 40 mg Filmtabletten; ZOCOR FORTE XL 80 mg Filmtabletten

Greece ZOCOR

Iceland ZOCOR

Ireland ZOCOR

Italy SINVACOR

Luxembourg ZOCOR

Netherlands ZOCOR

Norway ZOCOR

Portugal ZOCOR

Spain ZOCOR; ZOCOR FORTE (for 40 mg tablets)

Sweden ZOCORD

United Kingdom ZOCOR

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