

## **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 want 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 get 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 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
  - itraconazole or ketoconazole ( 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. Tell your doctor if any of the following applies to you:

- you consume large amounts of alcohol
- kidney problems
- thyroid problems
- you are more than 70 years old
- you have ever had muscle problems during treatment with cholesterol-lowering medicines called “statins” or fibrates
- you or close family members 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 or ketoconazole (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 used for an irregular heart beat)
- verapamil or diltiazem (medicines for high blood pressure, chest pain associated with heart disease, or other heart conditions)

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).

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**

‘Zocor’ is not recommended for use in children.

### **Driving and using machines**

‘Zocor’ is not expected to interfere with your ability to drive or 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.

## **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’ 5 mg, 10 mg, 20 mg, 40 mg or 80 mg tablet by mouth once a day.

The 80mg dose is only recommended in patients with very high cholesterol levels at high risk of heart disease problems.

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 80mg 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 the 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).

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).

Possible side effects reported with some statins:

- sleep disturbances, including trouble sleeping and nightmares
- sexual difficulties
- depression
- breathing problems including persistent cough and/or shortness of breath or fever.

#### *Laboratory Values*

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

If any of the side effects get 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 store above 25°C

Do not put them into another container as they might get mixed up.

If you have any tablets left over when your doctor tells you to stop taking them, return them to your doctor or pharmacist.

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

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 (10mg, 20mg, 40mg or 80mg).

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

### **What 'Zocor' looks like and the contents of the pack.**

'Zocor' Tablets are available in four strengths. The peach-coloured, oval-shaped, film-coated tablets marked 'MSD 735' on one side and plain on the other side contain 10 mg simvastatin. The tan-coloured, oval-shaped, film-coated tablets marked 'MSD 740' on one side and plain on the other side contain 20 mg simvastatin. The brick-red-coloured, oval-shaped, film-coated tablets marked 'MSD 749' on one side and plain on the other side contain 40 mg simvastatin. The brick-red coloured, capsule-shaped, film-coated tablets marked '543' on one side and '80' on the other contain 80 mg simvastatin.

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

'Zocor' Tablets are also available in white high density polyethylene or polypropylene bottles or amber glass bottles containing 50 tablets.

Not all pack sizes may be marketed.

## **MARKETING AUTHORISATION HOLDER AND MANUFACTURER**

The Marketing Authorisation Holder in the UK 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, 20mg and 40mg tablets is Merck Manufacturing Division, Merck Sharp & Dohme Limited, Shotton Lane, Cramlington, Northumberland NE23 3JU, UK.

The manufacturer of the 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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