

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What MEVACOR 20 mg Tablets is and what it is used for
2. Before you take MEVACOR 20 mg Tablets
3. How to take MEVACOR 20 mg Tablets
4. Possible side effects
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MEVACOR[®] 20 mg Tablets
(lovastatin)

Each tablet contains as active substance 20 mg of lovastatin.

The excipients are hydrated lactose, corn pregelatinized starch, cellulose microcrystalline, magnesium stearate, butylhydroxyanisole and aluminum lake blue FD&C N° 2.

License Holder:

MERCK SHARP & DOHME DE ESPAÑA, S.A
C/ Josefa Valcárcel, 38
28027 MADRID

Manufacturing responsible:

FROSST IBERICA S.A.
Vía Complutense, 140.
28805 Alcalá de Henares (Madrid)

1. WHAT MEVACOR 20 mg Tablets IS AND WHAT IT IS USED FOR

MEVACOR 20 mg is dispensed in a package of 28 scored tablets each containing 20 mg of lovastatin. The tablets are scored, octagonal, light blue and marked "MSD 731" on one side.

MEVACOR (lovastatin) reduces the level of cholesterol in your blood. It is a member of the class of drugs called hydroxymethylglutaryl-coenzyme A (HMG-CoA) reductase inhibitors.

MEVACOR decreases the production of cholesterol in the liver (the largest source of cholesterol within the body) and increases the removal of cholesterol from your bloodstream by the liver. In terms of LDL and HDL, MEVACOR significantly reduces LDL (bad cholesterol) and, in most patients, actually raises HDL (good cholesterol). By combining MEVACOR with your diet, you take control of the amount of cholesterol you eat and the amount your body produces.

MEVACOR reduces elevated cholesterol in patients with high cholesterol in blood (hypercholesterolemic patients) when the response to diet and other measures alone has been inadequate.

Treatment, together with an appropriate diet, to slow the progression of atherosclerosis (hardening of the arteries) in patients with hypercholesterolemia and coronary heart disease.

2. BEFORE YOU TAKE MEVACOR 20 mg Tablets

Do not take MEVACOR 20 mg Tablets:

- if you are allergic to lovastatin or to any of its components,
- if you are diagnosed with active liver disease,
- if you are pregnant or breast-feeding.
- if you are taking one of the following:
 - the antifungal agents (medicines used to treat fungal infections) itraconazole or ketoconazole.
 - the antibiotics erythromycin, clarithromycin, or telithromycin.
 - HIV protease inhibitors (such as indinavir, nelfinavir, zidovudine, and zalcitabine) (medicines used to treat HIV infections produced by AIDS).
 - the antidepressant nefazodone.

Take special care with MEVACOR 20 mg Tablets:

- **If you experience muscle pain, tenderness, or weakness.** Inform your doctor immediately. Rarely, MEVACOR can cause severe muscle problems that can produce renal impairment. This risk is higher in patients who take high doses of MEVACOR or who take, together with lovastatin, some medicine that increase lovastatin (active substance of MEVACOR) levels in blood, and therefore, the risk of suffering muscle disorders, such as:
 - Fibrates and niacin (medicines that reduce cholesterol levels)
 - Amiodarone and verapamil (medicines used to treat heart problems)
 - Ciclosporin (medicine used to prevent transplant rejection).

Tell your doctor about any medical problems you have or have had, and about any allergies.

Tell your doctor if you consume substantial quantities of alcohol or have a past history of liver disease.

Pregnancy:

MEVACOR is contraindicated during pregnancy.

In case of pregnancy or if it is suspected, you should discontinue the treatment and warn your doctor as soon as possible.

Ask your doctor or pharmacist before taking any medicine.

Breast-feeding:

Women taking MEVACOR should not breast-feed.

Ask your doctor or pharmacist before taking any medicine.

Children:

MEVACOR is not recommended for use in children.

Driving and using machines:

MEVACOR, at the recommended therapeutic doses, does not affect the capability of driving vehicles and handling machinery. However, if you experience dizziness symptoms, do not drive nor use machinery until you know how you tolerate the medicine.

Warning on excipients:

Due to the inclusion of butylhydroxyanisole as excipient this may produce irritation of eyes, skin and mucous membranes.

Taking other medicines:

Inform your doctor or pharmacist if you are using, or have recently used, any other medicines, even those not prescribed.

Certain medicines can interact with MEVACOR and can increase the risk of muscle adverse reactions (see **4. POSSIBLE SIDE EFFECTS**); in these cases, dosage adjustment or discontinue the treatment with any of the medicines can be necessary.

It is important that you inform your doctor if you are taking or have recently taken some of the following medicines:

- ciclosporin (medicine used to prevent transplant rejection).
- danazol (medicine used to treat endometriosis).
- antifungal agents (medicines used to treat fungal infections) (such as itraconazole or ketoconazole).
- fibric acid derivatives (such as gemfibrozil, bezafibrate, or fenofibrate) (other medicines for the treatment of cholesterol increase).
- the antibiotics erythromycin, clarithromycin, and telithromycin
- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir) (medicines used to treat HIV infections produced by AIDS).
- the antidepressant nefazodone
- amiodarone (a drug used to treat an irregular heartbeat)
- verapamil (a drug used to treat high blood pressure or angina)
- large doses (≥ 1 g/day) of niacin or nicotinic acid

It is also important to tell your doctor if you are taking anticoagulants (drugs that prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol).

3. HOW TO TAKE MEVACOR 20 mg Tablets

Follow these instructions unless your doctor gave you different advice.

Remember to take your medicine.

Your doctor has prescribed your dose of MEVACOR. The usual starting dose is 20 mg per day, given as a single dose with the evening meal. Some patients with mild to moderate hypercholesterolemia can be treated with an initial dose of 10 mg. Your doctor may adjust your dose to a maximum of 80 mg/day, given in a single dose with the evening meal or divided doses with the morning and evening meals. Your doctor may prescribe lower doses, particularly if you are taking certain of the medications listed above or have certain kidney conditions. Keep taking MEVACOR unless your doctor tells you to stop. If you stop taking MEVACOR, your cholesterol may rise again.

Try to take MEVACOR as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

Break the scored tablet of 20 mg if you need to obtain a 10 mg dose.

Most patients take MEVACOR with a drink of water.

If you have the impression that the effect of MEVACOR is too strong or too weak, talk to your doctor or pharmacist.

If you take more MEVACOR 20 mg Tablets than you should:

In case of overdosage or accidental ingestion, consult the Information Service of Toxicology. Telephone: (91) 562 04 20. Also contact your doctor immediately.

If you forget to take MEVACOR 20 mg Tablets:

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, MEVACOR can have side effects.

MEVACOR is generally well-tolerated. For the most part side effects have been mild and short-lived.

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

This risk of muscle breakdown is greater for patients taking higher doses of MEVACOR. This risk of muscle breakdown is greater for patients with abnormal kidney function.

The frequencies of adverse events are ranked according to the following: Very Common (>1/10), Common ($\geq 1/100$, <1/10), Uncommon ($\geq 1/1,000$, <1/100), Rare ($\geq 1/10,000$, <1/1000), Very Rare (<1/10,000).

Common >1% and < 10% (less than 1 person in every 10 but more than 1 person in every 100):

Gastrointestinal disorders: constipation, dyspepsia

Uncommon 0,1% to 1% (less than 1 person in every 100 but more than 1 person in every 1,000):

Skin and subcutaneous tissue disorders: itching

Rare 0,01% to 0,1% (less than 1 person in every 1,000):

Eye disorders: blurred vision

Gastrointestinal disorders: abdominal pain, diarrhea, dry mouth, flatulence, nausea, vomiting

General disorders and administration site conditions: weakness

Hepatic disorders: yellowing of the skin and eyes (cholestatic jaundice), hepatitis

Metabolism and nutrition disorders: loss of appetite

Musculoskeletal, connective tissue and bone disorders: muscle weakness (myopathy), tenderness and muscle pain, muscle cramps

Nervous system disorders: dizziness, absence of the sense of taste, headache, tingling sensation, tingling and numbness of the feet and legs

Psychiatric disorders: insomnia, psychic disturbances including anxiety, sleep disorders

Skin and subcutaneous tissue disorders: alopecia, spotted or diffuse redness of the skin including Stevens - Johnson syndrome, redness and swelling of the skin, shedding of the skin.

An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus-like syndrome, polymyalgia rheumatica, dermatomyositis, vasculitis, thrombocytopenia, leukopenia, eosinophilia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, flushing, chills, dyspnea and malaise.

Investigations:

Uncommon: elevated transaminases

Rare: other liver function test abnormalities including elevated alkaline phosphatase and bilirubin; increase in serum CK levels.

Other side effects may also occur rarely and, as with any prescription drug, some side effects may be serious. Ask your doctor or pharmacist for more information. Both have a more complete list of side effects.

Tell your doctor or pharmacist if you develop any unusual symptom or if any known symptom persists or worsens.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING MEVACOR 20 mg Tablets

Keep MEVACOR out of the reach and sight of children.

There are no special storage conditions.

Expiration:

Do not use MEVACOR after the expiry date on the carton.

This leaflet was approved on December 2004.