

MEDOSTATIN

Lovastatin (20mg, 40mg)

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What MEDOSTATIN is used for

MEDOSTATIN may reduce the risk of heart disease by helping to keep your arteries clear, even if your cholesterol levels are normal. MEDOSTATIN reduces the amount of cholesterol in your blood. MEDOSTATIN significantly reduces the level of LDL (bad) cholesterol and fatty substances called triglycerides in your blood and raises HDL (good) cholesterol. LDL-cholesterol is called “bad” cholesterol because it is the cholesterol that clogs your arteries. HDL, on the other hand, is thought to remove cholesterol from the blood vessels and is, therefore, considered to be “good” cholesterol.

How MEDOSTATIN works

Lovastatin belongs to the group of medicines known as statines or “HMG- CoA reductase inhibitors”. These work by reducing the amount of cholesterol and fatty substances called triglycerides in your blood. Cholesterol is vital to the normal functioning of the body, but if levels of cholesterol in the bloodstream are too high it can be deposited on the walls of the arteries. There it builds up to form plaques which can eventually block the blood vessel, just like scale furring-up a water pipe. We only get a small amount of cholesterol from our diet; egg yolks and liver contain large amounts of cholesterol, but many foods like fruit, vegetables, and fish are quite low in cholesterol. Nearly all of the cholesterol in our bodies is made by our own livers. The body produces the most cholesterol at night, which is why it is recommended that MEDOSTATIN is taken in the evening or at night.

Before you use MEDOSTATIN

When you must not use it

Do not take MEDOSTATIN:

- If you are allergic to lovastatin and any of the other ingredients of this medicine
- If you are pregnant or you are breastfeeding
- If you have liver problems

Pregnancy and Lactation

If you are pregnant or or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Lovastatin should not be administered during pregnancy. If you become pregnant while taking lovastatin, the drug should be discontinued and you should be informed again of the potential hazards to the foetus.

If you are taking this medicine and you are breast feeding a baby, you should discuss this with the doctor. Lovastatin should not be administered during breastfeeding.

Before you start to use it

Talk to your doctor or pharmacist before taking MEDOSTATIN:

- If you ever had previous allergic reactions to lovastatin or other statines before treatment (included rash, itching, swelling or suddenly increased difficulty in breathing)
- if you have unexplained muscle pain, tenderness or weakness
- if you have thyroid problems
- if you have ever had previous liver disorders or increased transaminases (liver transaminases should be monitored)
- if you or close family members have a hereditary muscle disorder
- if you have severe kidney problems
- **if you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition.**

Check with your doctor or pharmacist before taking lovastatin if you:

- Have severe respiratory failure

Taking other medicines

Tell your doctor or pharmacist if you

are taking, have recently taken or might take any other medicines, including:

- antibiotics: erythromycin
- fibrates (other cholesterol-lowering medicines such as gemfibrozil)
- niacin or nicotinic acid
- anticoagulants (drugs that prevent blood clots), such as warfarin
- immunosuppressive drugs

How to use MEDOSTATIN

How much to use

The usual starting dose is 20mg once a day given with the evening meal.

If you have very high cholesterol levels (more than 300 mg/dl under diet) the starting dose may be 40mg per day.

Your doctor may adjust your dose to a maximum of 80 mg per day, given as a single dose in the evening. The 80 mg dose is only recommended in patients with severe hypercholesterolemia and high risk cardiovascular complications. Your doctor may prescribe lower doses, particularly if you are taking certain medications listed above or have certain kidney conditions. Your doctor may need to change this dose in order to have the best effect. Do not take more or less than your doctor has prescribed.

Children

Lovastatin is not recommended for use in children and adolescents below 18 years of age because safety and efficacy of lovastatin in children has not been established.

When to use it

Your doctor will tell you how much MEDOSTATIN to take and when to take it. The number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are taking the medicine. Ask your doctor to explain more. Always follow the instructions of the doctor. The instructions should be on the label. If you are not sure, ask your doctor or pharmacist.

How long to use it

Keep taking your tablets for as long as your doctor has asked you to.

If you stop taking MEDOSTATIN, your cholesterol may rise again.

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If you forget to use it

If you forget to take a tablet, take one as soon as you remember. Do not take more medicine in one day than your doctor tells you to. Do not take two doses at the same time, or within one hour of each other. Try to separate them by at least four hours.

If you use too much (overdose)

Never take more than the prescribed dose. If you suspect that you or someone else has taken too many tablets contact your doctor or go to the accident and emergency department of your local hospital at once. Always take the container with you, if possible, even if it is empty.

While you are using it

Things you must do

- Take your medicine exactly as your doctor has told you
- Tell all doctors, dentists and pharmacists treating you that you are taking MEDOSTATIN
- Tell your doctor immediately if you become pregnant while taking this medication

Things you must not do

- Do not stop taking this medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give MEDOSTATIN to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Driving and using machines

MEDOSTATIN has no known effects on driving or operating machines.

Important information about some of the ingredients of MEDOSTATIN

MEDOSTATIN contains lactose. Take special care if you are lactose

intolerant and you cannot tolerate certain sugars and discuss it with your doctor before taking this medicine.

Side effects

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

Possible side effects

- Sleep disturbances, including insomnia and nightmares
- Memory loss
- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or fever

During or after treatment it is important to tell your doctor if you have:

- stomach upsets (such as sickness, constipation, diarrhoea, flatulence, indigestion and abdominal pain)
- dry mouth
- muscle cramps, muscle aches and pains, tenderness
- weakness, headache, dizziness
- numbness or loss of sensation in the arms and legs
- allergic reactions as a swelling of the face, tongue or throat (in which case you should contact your doctor immediately), joint pains, joint and blood vessel inflammation, unusual bruising, skin eruptions
- hair loss
- rash, itchiness
- blurred vision, eye irritation
- liver disease (possibly presenting as yellowing of the eyes and/or skin, itchiness of the skin, dark coloured urine, pale coloured stools)
- diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

Unknown frequency:

- Myasthenia gravis (a disease causing general muscle weakness

including in some cases muscles used when breathing).

- Ocular myasthenia (a disease causing eye muscle weakness).

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

Do not worry about this list of possible effects; you may not have any of them.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website bpfk.gov.my [Public → Reporting Side Effects to Medicines (ConSERF) of Vaccines (AEFI)].

Storage and disposal of MEDOSTATIN

Storage

Keep this medicine out of the sight and reach of children. This medicinal product does not require any special storage conditions

Disposal

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

What it looks like

MEDOSTATIN 20mg tablets are blue, round, flat, scored on one side. MEDOSTATIN 40mg tablets are white, round, flat, scored on one side.

The tablets are supplied in PVC-Al blisters. Each blister contains 10 tablets. Boxes containing 1, 3 or 10 blisters are available.

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Lovastatin (20mg, 40mg)

Not all pack sizes may be marketed.

Ingredients

Active

ingredients

The active substance is lovastatin as lovastatin.

Inactive ingredients

The other ingredients are: lactose monohydrate, starch maize pregelatinised, cellulose microcrystalline, butylated hydroxytoluene, magnesium stearate.

MEDOSTATIN 20mg tablets contain also indigotine blue aluminium lake (E132)

MAL No.

MEDOSTATIN Table 20mg

MAL19973311A

MEDOSTATIN Tablet 40mg

MAL20021411A

Manufacturer

MEDOCHEMIE LTD, (Central Factory), 1-10, Constantinopoleos Street, Limassol 3011, Cyprus

Product Registration Holder

KOMEDIC SDN BHD, 4 Jalan PJS 11/14, Bandar Sunway, 46150 Petaling Jaya

Date of Revision

03/09/2025

Serial Number

NPRA(R2/2)250902/1535