

Aterkey 20

Tablets
ORAL USE



COMPOSITION:

Each tablet contains:

Lovastatin (DCI)..... 20 mg

Excipients: Butylhydroxyanisol, lactose, pregelatinized starch, microcrystalline cellulose, magnesium stearate.

PHARMACEUTICAL FORMULATION AND PACKAGING CONTENTS:

Tablets

Packages containing 28 tablets.

ACTIVITY:

Lovastatin reduces cholesterol level in blood. It is a member of the medicines group called HMG-CoA reductase inhibitors.

Lovastatin diminishes cholesterol production in the liver (the main cholesterol source in the body) and increases cholesterol elimination of the blood system through the liver. Regarding LDL and HDL cholesterol, lovastatin diminishes LDL cholesterol (nocive cholesterol) dramatically and, in most of the patients, raises HDL cholesterol (beneficial cholesterol). By means of combining lovastatin with diet, the amount of cholesterol your body ingests and produces is controlled.

PROPRIETER AND MANUFACTURER:

INKEYSA, S.A.

Juan XXIII, 15-19

08950— Esplugues de Llobregat (Barcelona)

INDICATIONS:

Reduction of high cholesterol levels in patients with high cholesterol in blood (hypercholesterolemics) when response to diet and other measures have been inadequate alone.

Treatment together with the suitable diet to delay atherosclerosis advance (arterial enhardishment) in patients with hypercholesterolemia and coronary cardiopathy.

CONTRAINDICATIONS:

You should not take lovastatin:

- If you are allergic to any of its components (see section **Composition**);
- If you suffer from diagnosed active liver disease;
- If you are pregnant or in lactation time.

PRECAUTIONS:

Inform your doctor of your past and present medical problems, and of any allergy you suffer. Inform your doctor if you consume important amounts of alcohol or if you have ever experienced liver disease.

INTERACTIONS:

You should inform your doctor of all the medicines you are taking or intend to use, including those bought under no prescription. It is specially important your doctor knows if you are taking cyclosporin, antifungic agents (such as itraconazole), fibric acid derivatives (such as phenofibrate and gemfibrozil) or high doses (> 1 g/day) of niacine or nicotinic acid.

WARNINGS:

Pregnancy and lactation.

Fertile-aged women can take lovastatin only when they are very unlikely to get pregnant. If you think you get pregnant while having lovastatin, you should stop the treatment and consult your doctor immediately.

Women taking lovastatin should not breastfeed their children.

Effects on driving capacity.

Unknown.

Use in children.

The use of lovastatin in children is not recommended.

Warning on excipients.

The presence of butylhydroxyanisol may account on eyes, skin, and mucoses irritation.

DOSAGE:

The doctor has prescribed you your lovastatin dose.

The frequent initial dose is 20 mg/day, administered as single dose during dinner. Some patients suffering from mild to moderate hypercholesterolemia can begin the treatment as daily 10 mg lovastatin posology. The doctor can adjust the dose up to 80 mg/day, as a maximum, administered as a single dose during dinner, or in divided doses between lunch and dinner. The doctor can prescribe you lower doses, specially if you are taking cyclosporin or suffer from certain renal disorders. Keep on taking lovastatin until the doctor asks you to interrupt the treatment. If you stop taking lovastatin, your cholesterol may increase again.

Try to take lovastatin as the doctor has indicated you. However, if you forget to take a dose, do not take any extra one. Just follow the established treatment guideline.

INSTRUCTIONS FOR THE CORRECT ADMINISTRATION OF THE PREPARATION:

Divide the tablet of 20 mg into two parts if you want to obtain a 10 mg dose.

Most patients take lovastatin with a glass of water.

OVERDOSE:

If overdosing or accidental ingestion, consult the Poison Centre.

ADVERSE REACTIONS:

All the medicines may have undesirable or non intended effects, called adverse reactions.

In general, lovastatin is adequately tolerated. In most cases, adverse reactions have been mild and short-length. The most frequent adverse reactions are: digestive disorders, dizziness, altered vision, headache and rash. Less frequent adverse reactions are: pain, muscular weakness, sensitivity to pressure, hepatic problems and hypersensitivity (allergic reactions which may have different symptoms, including articular pain, fever or breathing difficulties).

As muscular problems are seldom serious, you should consult your doctor rapidly if you show pain, muscular weakness.

Also, other adverse reactions might occur, as well as with any prescribed medicine, some of them might be serious. Ask your doctor or chemist for further information. Both have at their disposal a more complete list of adverse reactions.

If you notice any other adverse reaction not previously reported, consult your doctor or chemist.

PRESERVING:

Keep the medicine under 30°C of temperature. Protect from the sunshine and keep in the original package.

CADUCITY:

This medicine should not be used after the expiry date stated in the packaging.

DRUGS SHOULD BE KEPT OUT OF CHILDREN'S REACH.

UNDER PRESCRIPTION.

Last revision of the text: May 2000.

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