

PATIENT INFORMATION LEAFLET

Lovastatin Arya 20

Lovastatin 20 mg Scored Tablet

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

- Keep this leaflet. You may need to read it again.
- This medicine is not available without prescription.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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1. What Lovastatin Arya 20 is and what it is used for

-ATC code: C10AA02

Lovastatin Arya 20 belongs to a group of medicines called statins. Lovastatin Arya 20 is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. If you are at an increased risk of heart disease, Lovastatin Arya 20 can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.

2. What you need to know before you take Lovastatin Arya 20

-**Contraindications:** allergy to Lovastatin Arya 20 or any of the other ingredients of this medicine, active liver disease or unexplained persistent elevated liver function tests; pregnancy, lactation

-**Warnings and precautions:**

You should consult your doctor before taking these tablets if:

- you have problems with your kidneys.
- you have problems with your liver.
- you have had a previous stroke with bleeding into the brain, or have small pockets of fluid in the brain from previous strokes.
- you have had repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines.
- you regularly drink large amounts of alcohol.

-**Other important information:** this drug may cause photosensitivity (sensitivity to sunlight). Avoid prolonged exposure to the sun and other ultraviolet light. Use sunscreens and wear protective clothing until tolerance is determined. Follow dietary and exercise recommendations.

It is recommended that liver function tests be performed before the initiation of treatment, at 6 and 12 weeks after initiation of therapy or elevation in dose, and periodically thereafter.

-**Children, adolescents and elderly:** Lovastatin Arya 20 is indicated for treatment of patients 10 to 17 years of age with heterozygous familial hyper-cholesterolemia.

Elderly: The safety and efficacy of Lovastatin Arya 20 in patients 70 years of age and older were similar to those of patients younger than 70 years of age.

-**Other medicines and Lovastatin Arya 20:** Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

Warfarin, amiodarone, azole antifungals (e.g., itraconazole, ketoconazole), bile acid sequestrants (BAS) (e.g., colestipol, cholestyramine), diltiazem, fibric acid derivatives (e.g., gemfibrozil), Isradipine, macrolides (erythromycin, clarithromycin), nefazodone, niacin, protease Inhibitors (e.g., nelfinavir, ritonavir), verapamil

-**Lovastatin Arya 20 with food and drink:** Lovastatin Arya 20 should be given with food (evening meal). Do not drink alcohol and grapefruit juice in large amount while taking the medicine.

-**Pregnancy and breast-feeding:** Do not take Lovastatin Arya 20 if you are pregnant or breast-feeding. (FDA Pregnancy Category: X) If you become pregnant while taking Lovastatin Arya 20 stop taking it immediately and tell your doctor.

-**Driving and using machines:** Lovastatin Arya 20 has no or negligible influence on the ability to drive or use machines, but do not drive or operate heavy machinery unless you know how Lovastatin Arya 20 affects you.

3. How to take Lovastatin Arya 20

Always take this medicine exactly as your doctor or pharmacist tyou. Check with your doctor or pharmacist if you are not sure.

Recommended dose:

-**Adults:** Initial dose for Lovastatin Arya 20 is 20 mg orally once daily. increase if necessary up to 80 mg (single dose or divided into 2 doses), dose to be increased at intervals of at least 4 weeks

-**You should not take more tablets** than your doctor tells you to. If you take too many tablets, contact your doctor, pharmacist or hospital and take your medicine with you.

-**If you forget to take Lovastatin Arya 20,** take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Lovastatin Arya 20 can have side effects, although not everybody gets them.

Common: headache, diarrhea, arthralgia and myalgia, wind (flatulence), infection, flu syndrome, back pain

Uncommon: anorexia, insomnia, peripheral edema, dyspepsia, abdominal pain, heartburn

Rare: cholestasis, rash, dry mouth, Stevens-Johnson syndrome

5. How to store Lovastatin Arya 20

Keep out of the reach of children. Do not take after the expiry date stated on the blister and carton. The expiry date refers to the last day of that month. Protect from moisture and light at a temperature of no higher than 30°C.

6. Contents of the pack and other information

-**What Lovastatin Arya 20 contains:** Each tablet contains 20 mg lovastatin as active substance.

-**What Lovastatin Arya 20 looks like and what is in the pack:**

Lovastatin Arya 20 is available as round, biconvex, scored blue tablets in three white opaque Alu-PVC blister packs of ten tablets each carton box.

Manufacturer:

Arya Pharmaceutical Company

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