Evostatin

(Rosuvastatin)

10mg & 20mg Film Coated Tablets

ایووسٹیٹن

(روزواسٹیٹن)

۱۰ ملی گرام ۲۰ ملی گرام گولیاں

COMPOSITION
Evostatin 10mg
Each film coated tablet contains:
Rosuvastatin (as Rosuvastatin Calcium) 10mg

Evostatin 20mg
Each film coated tablet contains:
Rosuvastatin (as Rosuvastatin Calcium) 20mg

INDICATIONS
Evostatin contains the active ingredient rosuvastatin, which belongs to a group of medicines called statins. This medication is prescribed when you have a high cholesterol level. This means you are at risk from a heart attack or stroke. Rosuvastatin is used in adults, adolescents and children 6 years or older to treat high cholesterol or when changing diet and doing more exercise were not enough to correct cholesterol levels or have other factors that increase your risk of having a heart attack, stroke or related health problems.

- Rosuvastatin is used to correct the levels of fatty substances in the blood called lipids, the most common of which is cholesterol.
- Rosuvastatin can reduce the 'bad' cholesterol (LDL-C) and increase the 'good' cholesterol (HDL-C).
- It works by helping to block your body's production of 'bad' cholesterol. It also improves your body's ability to remove it from your blood.

- You need to keep taking Rosuvastatin, even if it has got your cholesterol to the right level, because it prevents your cholesterol levels from creeping up again and causing buildup of fatty deposits. However, you should stop if your doctor tells you to do so, or you have become pregnant.

CONTRAINDICATIONS
- If you are allergic to rosuvastatin.
- If you are pregnant or breast-feeding. If you become pregnant while taking rosuvastatin, stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking rosuvastatin by using suitable contraception.
- If you have liver disease.
- If you have severe kidney problems.
- If you have repeated or unexplained muscle weakness, aches or pains.
- If you take a drug combination of sofosbuvir/velpatasvir/voxilaprevir (used for viral infection of the liver called hepatitis C).
- If you take a drug called ciclosporin (used, for example, after organ transplants).

If any of the above applies to you (or if you are in doubt), please see your doctor.

WARNINGS AND PRECAUTIONS
Talk to your doctor or pharmacist before taking Evostatin
- If you have problems with your kidneys or liver.
- If you have a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Rosuvastatin or other related medicines.
- If you regularly drink large amounts of alcohol.
- If your thyroid gland is not working properly.
- If you take other medicines called fibrates to lower your cholesterol
- If you take medicines used to fight the HIV infection e.g. lopinavir/ritonavir and/or atazanavir, please see 'Other medicines and Rosuvastatin'.
- If you are taking or have taken in the last 7 days a medicine called fusidic acid (a medicine for bacterial infection), orally or by injection. The combination of fusidic acid and Rosuvastatin can lead to serious muscle problems (rhabdomyolysis). Please see 'Other medicines and Rosuvastatin '.
- If you have severe respiratory failure.
- If you are of Asian origin - that is Japanese, Chinese, Filipino, Vietnamese, Korean, Pakistani or Indian. Your doctor needs to choose the right start dose of Rosuvastatin to suit you.

Children and adolescents
- If the patient is under 6 years old: Rosuvastatin should not be given to children younger than 6 years.
- If the patient is below 18 years of age: The Rosuvastatin 40 mg dose is not suitable for use in children and adolescents below 18 years of age.

DRUG INTERACTIONS
Rosuvastatin might interact with following drugs:
- ciclosporin (used for example, after organ transplants)
- warfarin, ticagrelor or clopidogrel (or any other drug used for thinning the blood)
- fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe)
- indigestion remedies (used to neutralise acid in your stomach)
- erythromycin (an antibiotic)
- fusidic acid (an antibiotic - please see 'Warnings and precautions')
- an oral contraceptive (the pill)
- regorafenib (used to treat cancer)
- darolutamide (used to treat cancer)
- hormone replacement therapy
- any of the following drugs used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see Warnings and precautions): ritonavir, lopinavir, atazanavir, sofosbuvir.

Pregnancy and breast-feeding
Do not take evostatin if you are pregnant or breast-feeding. If you become pregnant while taking this medicine stop taking it immediately and tell your doctor. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

If you forget to take Evostatin
Don't worry: just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Evostatin
Talk to your doctor if you want to stop taking Evostatin. Your cholesterol levels might increase again. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

SIDE EFFECTS
Like all medicines, this medicine can cause side effects, although not everybody gets them.
It is important that you are aware of what these side effects may be. They are usually mild and disappear after a short time, however some can be serious and require medical attention.

Common (may affect up to 1 in 10 people):
- Headache, Stomach pain, Constipation, Feeling sick, Muscle pain, Feeling weak, Dizziness.
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your Rosuvastatin tablets.

Uncommon (may affect up to 1 in 100 people):
- Rash, itching, itchy rash with raised lumps (hives)
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your Rosuvastatin tablets (only Rosuvastatin 10 mg and 20 mg).

Rare (may affect up to 1 in 1,000 people):
- Increase in liver enzymes, as seen in blood tests.

DOSAGE AND ADMINISTRATION
The dose range for Evostatin in adults is 5 to 40 mg orally once daily. The usual starting dose is 10 to 20 mg once daily. Evostatin can be administered as a single dose at any time of day, with or without food. The tablet should be swallowed whole.

For Adults: Starting dose in adult patients with homozygous familial hypercholesterolemia is 20 mg once daily. The maximum dose of 40 mg should be used only for those patients who have not achieved their LDL-C goal utilizing the 20 mg dose. After initiation of therapy lipid levels should be analyzed within 2 to 4 weeks and the dosage adjusted accordingly.

For Children age 8 to 17 Years: Dosing In heterozygous familial hypercholesterolemia, the recommended dose range is 5 to 10 mg orally once daily in patients 8 to less than 10 years of age, and 5 to 20 mg orally once daily in patients 10 to 17 years of age. In homozygous familial hypercholesterolemia, the recommended dose is 20 mg orally once daily in patients 7 to 17 years of age.

STORAGE CONDITIONS AND INSTRUCTIONS
- Store below 30˚C in a dry place, protect from light.
- To be dispensed on the prescription of a registered medical practitioner only.
- Keep out of the reach of children.

PRESENTATION
Evostatin 10mg tablet is available in blister pack of 10's.
Evostatin 20mg tablet is available in blister pack of 10's.

ہدایات:
- **خوراک** ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو ۳۰°C سے کم گرمی سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

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