

Astatin Tablets

Atorvastatin 10mg, 20mg, 40mg, 80mg

What is in this leaflet

1. What Astatin is used for
2. How Astatin works
3. Before you use Astatin
4. How to use Astatin
5. While you are using it
6. Side Effects
7. Storage and Disposal of Astatin
8. Product Description
9. Manufacturer
10. Product Registration Holder
11. Date of Revision

What Astatin is used for

Astatin 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, Astatin 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.

How Astatin works

Astatin works by reducing the amount of cholesterol made by the liver. In terms of good and bad cholesterol, Astatin reduces the bad cholesterol and raises the good cholesterol.

Before you use Astatin

When you must not use it

Do not take Astatin

- if you are hypersensitive (allergic) to Astatin or to any similar medicines used to lower blood lipids or to any of the other ingredients of the medicine.
- if you have or have ever had a disease which affects the liver
- if you have had any unexplained abnormal blood tests for liver function
- if you are a woman able to have children and not using reliable contraception

- if you are pregnant or trying to become pregnant
- if you are breast-feeding.

Before you start to use it

Talk to your doctor, pharmacist or nurse before taking Astatin:

- if you have a history of liver disease;
- if you have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems;
- if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other '-statin' or '-fibrate' medicines);
- if you have kidney problems;
- if you have had a previous stroke with bleeding into the brain, or have small pockets of fluid in the brain from previous strokes;
- if you have diabetes;
- if you regularly drink a large amount of alcohol.

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your treatment with Astatin to predict your risk of muscle-related side effects. The risk of muscle-related side effects is known to increase when certain medicines are taken at the same time. Your doctor will also carry out a blood test before and during treatment to check if your liver is working properly.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if you are taking:

- medicines used to alter the way your immune system works (e.g. cyclosporine);
- certain antibiotics or antifungal medicines (e.g. erythromycin, clarithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, rifampin, fusidic acid);
- other lipid lowering medicine (e.g. gemfibrozil and other fibrates, colestipol, niacin);
- medicines used in the treatment of HIV (e.g. efavirenz, ritonavir, lopinavir, indinavir, darunavir);
- some medicines used for angina (chest pain) or high blood pressure (e.g. amlodipine, diltiazem), medicines to regulate your heart rhythm (e.g. digoxin);
- some medicines used in the treatment of hepatitis C (e.g. telaprevir, boceprevir);
- other medicines known to interact with Astatin include warfarin (which reduces blood clotting), oral contraceptives, cimetidine (used for heartburn and peptic ulcers), antacids (containing magnesium or aluminium for indigestion).

How to use Astatin

How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The usual starting dose of Astatin is 10 mg once a day in adults and children aged 10 or older. This may be increased if

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necessary by your doctor until you are taking the amount you need. Your doctor will adapt the dose at intervals of 4 weeks or more. The maximum dose of Astatin is 80 mg once daily for adults and 20 mg once daily for children.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

Continue taking Astatin for as long as your doctor recommends.

If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

Things to must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Astatin.

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Astatin to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

Normally this medicine does not affect your ability to drive or operate machines.

Side Effects

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

Frequent side effects:

- inflammation of the nasal passages, pain in the throat, nose bleed, increase in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels);
- diarrhoea, indigestion, nausea, wind;
- painful, swollen joints, pain in the hands or ankles, muscle pain and cramps;
- blood test results that show your liver function can become abnormal, increase in blood creatine kinase (an enzyme indicating muscle damage).

Other possible side effects:

- nightmares;
- blurred vision;
- ringing in the ears;
- stomach pain, belching;
- hepatitis (liver inflammation), cholestasis (yellowing of the skin and whites of the eyes);
- skin rash and itching (hives);
- muscle fatigue, neck pain;

- feeling unwell, raised temperature;
- urine tests that are positive for white blood cells.

Side effects reported during post-marketing experience:

- reduction in blood platelets which increases the risk of bleeding or bruising, allergic reactions (including serious allergic reaction which causes difficulty in breathing or dizziness), tendon injury;
- weight gain;
- reductions of sensation to pain or touch;
- loss of memory, dizziness, change in sense of taste;
- pancreatitis (inflammation of the pancreas leading to stomach pain);
- severe skin reactions which can cause blisters, sores and ulceration;
- muscle weakness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown;
- back pain, chest pain, swelling especially in the ankles, fatigue.

If you have muscle problems that do not go away even after your doctor has told you to stop taking Astatin, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Consumers -> Reporting -> Reporting Side Effects to Medicines

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(ConSERF) or Vaccines
(AEFI))

Storage and Disposal of Astatin

Storage

Store below 30°C. Protect from moisture.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

10mg: White colored, oval shaped, biconvex film coated tablets with one side embossed "10" and other side plain.

20mg: White colored, oval shaped, biconvex film coated tablets with one side embossed "20" and other side plain.

40mg: White colored, oval shaped, biconvex film coated tablets with one side embossed "40" and other side plain.

80mg: White colored, oval shaped, biconvex film coated tablets with one side embossed "80" and other side plain.

Ingredients

Active ingredient

Atorvastatin

Inactive ingredients

Mannitol, Sodium Lauryl Sulfate, Ethanol, Colloidal Anhydrous Silica, Anhydrous Sodium Carbonate, Butylated Hydroxyanisole, Microcrystalline Cellulose, Croscarmellose Sodium, Magnesium Stearate, Sepifilm LP 010, Purified Water

MAL numbers

Astatin 10mg Tablets:

MAL17085045ACZ

Astatin 20mg Tablets:

MAL17085047ACZ

Astatin 40mg Tablets:

MAL17085048ACZ

Astatin 80mg Tablets:

MAL17085046ACZ

Manufacturer

Ind-Swift Limited

Off NH-21, Village
Jawaharpur, Tehsil Derabassi,
District S.A.S. Nagar (Mohali),
Punjab-140507, India.

Product Registration Holder

Apex Pharmacy Marketing Sdn
Bhd

No. 2, Jalan SS 13/5, 47500
Subang Jaya, Selangor,
Malaysia

Date of Revision

June 2019

Serial Number

NPRA(R2/1)190621/174