

APO-ATORVASTATIN TABLET

Atorvastatin Calcium (20mg, 40mg, 80mg)

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What Apo-Atorvastatin is used for

Atorvastatin is used to lower the levels of cholesterol (particularly Low Density Lipoprotein (LDL) cholesterol) and other fats in the blood. This may help prevent heart disease is caused by cholesterol clogging the blood vessels or slow the progression of atherosclerosis (hardening of the arteries that nourish your heart), so-called coronary heart disease (CHD).

How Apo-Atorvastatin works

Apo-Atorvastatin inhibits an enzyme that is necessary for the body to make cholesterol. In this way, less cholesterol is produced in the liver.

Before you use Apo-Atorvastatin

- When you must not use it

Tell your physician if

- You have previously taken atorvastatin or any other medication in the same class -example, simvastatin, pravastatin or fluvastatin and were allergic, or had reacted badly to it.
- You are pregnant or intend to become pregnant. This medicine should not be used during pregnancy.
- You are breast-feeding, or intend to breast-feed.
- You have other medical conditions, especially liver disease.

Pregnancy and lactation

Do not take Apo-Atorvastatin if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Apo-Atorvastatin if you are breast-feeding. Ask your doctor or

pharmacist for advice before taking any medicine.

• Before you start use it

Apo-Atorvastatin may not be suitable for you:

- If you have kidney problems
- 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 regularly drink a large amount of alcohol
- If you have a history of liver disease

Talk to your doctor or pharmacist before taking Apo-Atorvastatin:

- 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.

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your Apo-Atorvastatin treatment to predict your risk of muscle related side effects.

• 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.

Taking atorvastatin together with fibrates might cause severe myositis (muscle inflammation), or myoglobinuria (loss of myoglobin due to muscle damage).

Other medications which involves the cytochrome P450 3A4 (A protein used to break down atorvastatin), such as erythromycin, protease inhibitors, and even drinks such as grapefruit juice will increase the plasma level of atorvastatin in your body when used concomitantly with Atorvastatin.

How to use Apo-Atorvastatin

• 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.

• When to use it

Use as directed by your doctor or pharmacist.

• How long to use it

Continue taking Apo-Atorvastatin 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 taking Apo-Atorvastatin

• Things you 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 Apo-Atorvastatin. 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 Apo-Atorvastatin to anyone else, even if they have the same symptoms or condition as you.

• **Things to be careful of**

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side Effects

Like all medicines, Apo-Atorvastatin can cause side effects, although not everybody gets them.

Side effects you could have while taking Apo-Atorvastatin include

- Aching muscles, muscle cramps, tiredness or weakness
- Fever

Some other side effects that may occur, generally do not require medical attention, and may come and go during treatment. But if any of the following persist or become troublesome, do check with your physician or pharmacist:

- Constipation, diarrhea, gas, stomach upset, nausea
- Pain in the abdomen
- Headache, dizziness
- Skin rash

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.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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

Storage and Disposal of Apo-Atorvastatin

- **Storage**

Keep out of the reach and sight of children.

Store below 30°C.

- **Disposal**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product Description

- **What it looks like**

20 mg: White, oval, biconvex film-coated tablets. Engraved "APO" on one side, "ATV20" on the other side.

40 mg: White, oval, biconvex film-coated tablets. Engraved "APO" on one side, "ATV40" on the other side.

80 mg: White, oval, biconvex film-coated tablets. Engraved "APO" on one side, "ATV80" on the other side.

20mg: Blister pack of 30s, HDPE bottles of 90s and 100s

40mg: Blister pack of 30s, HDPE bottles of 60s

80mg: Blister pack of 30s, HDPE bottles of 30s

- **Ingredients**

- Active ingredient(s)
Atorvastatin calcium

- Inactive ingredients

Calcium Acetate, Croscarmellose Sodium, Sodium Carbonate Anhydrous, Microcrystalline Cellulose, Magnesium Stearate, Colloidal Silicon Dioxide, Hydroxy Propyl Methyl Cellulose, Hydroxy Propyl Cellulose, Polyethylene Glycol and Titanium Dioxide.

- **MAL number:**

Apo-Atorvastatin
20mg: MAL15085003ARZ

Apo-Atorvastatin
40mg: MAL15085004AZ

Apo-Atorvastatin
80mg: MAL15085005AZ

Manufacturer

Apotex Inc.
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Canada

Product Registration Holder

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