

PATIENT INFORMATION
Atorvastatin Calcium Tablets, USP
(a tor' va stat' in kal' see um)
for oral use

What is atorvastatin calcium tablets?

Atorvastatin calcium tablets is a prescription medicine that contains a cholesterol lowering medicine (statin) called atorvastatin. Atorvastatin calcium tablets are used:

- to reduce the risk of:
 - heart attack, stroke, certain types of heart surgery and chest pain in adults who do not have heart disease but have other multiple risk factors for heart disease.
 - heart attack and stroke in adults with type 2 diabetes mellitus who do not have heart disease but have other multiple risk factors.
 - heart attack that does not cause death, stroke, certain types of heart surgery, hospitalization for congestive heart failure, and chest pain in adults with heart disease.
- along with diet to reduce low density lipoprotein cholesterol (LDL-C) or bad cholesterol:
 - in adults with primary hyperlipidemia.
 - in adults and children aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH). This is an inherited condition that causes high levels of bad cholesterol.
- along with other cholesterol lowering treatments or alone if such treatments are unavailable in adults and children aged 10 years and older with homozygous familial hypercholesterolemia (HoFH). This is an inherited condition that causes high levels of bad cholesterol.
- along with diet for the treatment of adults with:
 - primary dysbetalipoproteinemia (an inherited condition that causes high levels of cholesterol and fat).
 - hypertriglyceridemia.

It is not known if atorvastatin calcium tablets are safe and effective in children younger than 10 years of age with HeFH or HoFH or in children with other types of hyperlipidemias (other than HeFH or HoFH).

Do not take atorvastatin calcium tablets if you:

- have liver problems (acute liver failure or decompensated cirrhosis)
- are allergic to atorvastatin or any of the ingredients in atorvastatin calcium tablets. Stop using atorvastatin calcium tablets and get medical help right away if you have symptoms of a serious allergic reaction including:
 - swelling of your face, lips, tongue or throat
 - problems breathing or swallowing
 - fainting or feeling dizzy
 - very rapid heartbeat
 - severe skin rash or itching
 - flu-like symptoms including fever, sore throat, cough, tiredness, and joint pain

See the end of this leaflet for a complete list of ingredients in atorvastatin calcium tablets.

Before you take atorvastatin calcium tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have unexplained muscle aches or weakness

- drink more than 2 glasses of alcohol daily
- have diabetes
- have thyroid problems
- have kidney problems
- had a stroke
- are pregnant or plan to become pregnant. Atorvastatin calcium tablets may harm your unborn baby. If you become pregnant, stop taking atorvastatin calcium tablets and call your healthcare provider right away.
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take atorvastatin calcium tablets or breastfeed. You should not do both. Talk to your healthcare provider about the best way to feed your baby if you take atorvastatin calcium tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Atorvastatin calcium tablets and certain other medicines can increase the risk of muscle problems or other side effects. Especially tell your healthcare provider if you take medicines for:

- your immune system (cyclosporine)
- cholesterol (gemfibrozil)
- infections (erythromycin, clarithromycin, itraconazole, ketoconazole, posaconazole, and voriconazole)
- birth control pills
- heart failure (digoxin)
- gout (colchicine)
- niacin
- fibrates
- treating HIV, AIDS, or hepatitis C (anti-virals)
 - tipranavir plus ritonavir
 - ledipasvir plus sofosbuvir
 - saquinavir plus ritonavir
 - fosamprenavir
 - elbasvir plus grazoprevir
 - nelfinavir
 - glecaprevir plus pibrentasvir
 - simeprevir
 - darunavir plus ritonavir
 - fosamprenavir plus ritonavir
 - letermovir

Ask your healthcare provider or pharmacist for a list of medicines if you are not sure. Know all the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take atorvastatin calcium tablets?

- Take atorvastatin calcium tablets exactly as your healthcare provider tells you to take them.
- Do not change your dose or stop atorvastatin calcium tablets without talking to your healthcare provider.
- Your healthcare provider may do blood tests to check your cholesterol levels during your treatment with atorvastatin calcium tablets. Your dose of atorvastatin calcium tablets may be changed based on these blood test results.
- Take atorvastatin calcium tablets each day at any time of day. Atorvastatin calcium tablets can be taken with or without food.
- Your healthcare provider may start you on a cholesterol lowering diet before giving you atorvastatin calcium tablets. Stay on this low-fat diet when you take atorvastatin calcium tablets.

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- If you miss a dose of atorvastatin calcium tablets, wait and take the next dose at your regular time. Do not take 2 doses of atorvastatin calcium tablets at the same time.
- If you take too much atorvastatin calcium tablets or overdose, call your healthcare provider or Poison Control Center at 1-800-222-1222 or go to the nearest emergency room right away.

What should I avoid while taking atorvastatin calcium tablets?

- Avoid drinking more than 1.2 liters of grapefruit juice each day.

What are the possible side effects of atorvastatin calcium tablets?

Atorvastatin calcium tablets may cause serious side effects including:

- **Muscle pain, tenderness and weakness (myopathy).** Muscle problems, including muscle breakdown, can be serious in some people and, rarely, cause kidney damage that can lead to death.

Tell your healthcare provider right away if you have:

- unexplained muscle pain, tenderness, or weakness, especially if you also have a fever or feel more tired than usual while you take atorvastatin calcium tablets.
- muscle problems that do not go away after your healthcare provider has told you to stop taking atorvastatin calcium tablets. Your healthcare provider may do further tests to diagnose the cause of your muscle problems.

Your chances of getting muscle problems are higher if you:

- are taking certain other medicines while you take atorvastatin calcium tablets
- drink large amounts of grapefruit juice
- are 65 years of age or older
- have thyroid problems (hypothyroidism) that are not controlled
- have kidney problems
- are taking higher doses of atorvastatin calcium tablets

- **Liver problems.** Your healthcare provider should do blood tests to check your liver before you start taking atorvastatin calcium tablets and if you have symptoms of liver problems while you take atorvastatin calcium tablets. Call your healthcare provider right away if you have the following symptoms of liver problems:

- feel tired or weak
- nausea or vomiting
- loss of appetite
- upper belly pain
- dark amber colored urine
- yellowing of your skin or the whites of your eyes

- **Increase in blood sugar level.** Your blood sugar level may increase while you are taking atorvastatin calcium tablets.

Exercise regularly and make healthy food choices to maintain healthy body weight.

The most common side effects of atorvastatin calcium tablets include:

- nasal congestion,
- sore throat, runny nose
- diarrhea
- urinary tract infection
- nausea
- muscle spasms
- throat pain
- muscle and joint pain
- pain in extremity
- upset stomach
- musculoskeletal pain
- trouble sleeping

Talk to your healthcare provider or pharmacist if you have side effects that bother you or that will not go away.

These are not all the side effects of atorvastatin calcium tablets. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How do I store atorvastatin calcium tablets?

- Store atorvastatin calcium tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not keep medicine that is out of date or that you no longer need.
- **Keep atorvastatin calcium tablets and all medicines out of the reach of children.**

General information about the safe and effective use of atorvastatin calcium tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use atorvastatin calcium tablets for a condition for which it was not prescribed. Do not give atorvastatin calcium tablets to other people, even if they have the same symptoms that you have. It may harm them. If you would like more information about atorvastatin calcium tablets, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about atorvastatin calcium tablets that is written for health professionals.

What are the ingredients in atorvastatin calcium tablets?

Active Ingredient: atorvastatin calcium

Inactive Ingredients: Calcium carbonate, croscarmellose sodium, hydroxyl propyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate 80. The tablet coating contains hypromellose, polyethylene glycol, talc and titanium dioxide.

Rx only

Distributor:

Dr. Reddy's Laboratories Inc.,

Princeton, NJ 08540

Made in India

For more information, call Dr. Reddy's at 1-888-375-3784.

This Patient Package Information has been approved by the U.S. Food and Drug Administration

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Dispense with Patient Information Sheet available at:
www.drreddys.com/pi/atorvastatincryslite.pdf

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