

ZARATOR[®] FILM-COATED TABLETS

Crystalline Atorvastatin calcium (10 mg, 20 mg, 40 mg or 80 mg)

PLD Title	: Atorvastatin calcium (ZARATOR)
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Reason for Change	: TW3938971 - HA request to align labels between Zarator and Lipitor. TW3926053 - HA request for concerning signal of photosensitivity reaction and photodermatosis

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What ZARATOR is used for

ZARATOR belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

ZARATOR is used to lower lipids known as cholesterol [total cholesterol, low-density lipoprotein cholesterol (LDL-C)], apolipoprotein B (apo B) and other fats (triglycerides) and to increase high density lipoprotein cholesterol (HDL-C) in the blood when a low-fat diet and lifestyle changes on their own have failed.

ZARATOR can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as:

- Age, smoking, high blood pressure, low HDL-C, heart disease in the family.

ZARATOR can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as:

- Eye problems, kidney problems, smoking, or high blood pressure.

Cholesterol:

Everyone has cholesterol and triglycerides in their blood. They are types of blood fat needed by the body for many things, including building cell walls, making bile acids (which help to digest food) and certain hormones. However, too much cholesterol can be a problem.

Your body makes cholesterol, but it also comes from food. Normally the body balances the cholesterol it makes with the cholesterol it gets from food. This means

if more cholesterol comes from food, less is made by the body. However, if you eat a diet high in fat, your body may not keep this balance and your cholesterol levels rise. High cholesterol is more likely to occur with certain diseases or if you have a family history of high cholesterol. When you have high levels of cholesterol, it may 'stick' to the inside of your blood vessels instead of being carried to the parts of the body where it is needed. Over time, this can form hard areas, called plaques, on the walls of blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to coronary heart disease (such as heart attack and chest pain) and stroke. Other factors that will increase the risk of heart disease include high blood pressure, diabetes, increased weight, lack of exercise, smoking or a family history of heart disease.

There are different types of cholesterol, called low-density lipoprotein (LDL) and high-density lipoprotein (HDL). LDL cholesterol is the 'bad' cholesterol that can block your blood vessels. HDL cholesterol, on the other hand, is the 'good' cholesterol that is thought to remove the bad cholesterol from the blood vessels.

Triglycerides:

Triglycerides are an energy source for the body. However, as with cholesterol, too much triglycerides can be a problem.

How ZARATOR works

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

Before you use ZARATOR

- *When you must not use it*

Do not take ZARATOR

- if you are hypersensitive (allergic) to ZARATOR or to any of the other ingredients of the medicine;
- if you have active liver disease;
- if you have had any unexplained abnormal blood tests for liver function;
- if you are a woman of child-bearing capacity and not using any type of

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

- *Pregnancy and lactation*

- Do not take ZARATOR if you are pregnant, or if you are trying to become pregnant.
- Do not take ZARATOR if you are able to become pregnant unless you use reliable contraceptive measures.
- Do not take ZARATOR if you are breast-feeding.
- The safety of ZARATOR during pregnancy and breast-feeding has not yet been proven. Ask your doctor or pharmacist for advice before taking any medicine.

- *Before you start to use it*

You should continue on a standard cholesterol-lowering diet.

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

- if you have a history of liver disease, your doctor should perform a liver function test before initiating you on treatment;
- 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 muscle weakness with minimal inflammation
- 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 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 or lead to the occurrence of myasthenia.

If any of these apply to you, your doctor

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will need to carry out a blood test before and possibly during your treatment with ZARATOR 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.

In particular tell your doctor if you are taking:

- grapefruit juice;
- medicines used to alter the way your immune system works (e.g. cyclosporine);
- certain antibiotics or antifungal medicines (e.g., erythromycin, clarithromycin, rifampin, fusidic acid, azole antifungals like itraconazole);
- if you need to take fusidic acid to treat a bacterial infection your doctor may advise you to temporarily stop using ZARATOR. If you need to take fusidic acid for long periods along with this medicine, your doctor will consider on a case by case basis and under close medical supervision.
- other lipid lowering medicines (e.g. fibrates, colestipol, niacin);
- antivirals called protease inhibitors used in the treatment of HIV (e.g., tipranavir/ritonavir, lopinavir/ritonavir, saquinavir/ritonavir, darunavir/ritonavir, fosamprenavir, fosamprenavir/ritonavir, nelfinavir, efavirenz) and hepatitis C (telaprevir, boceprevir, glecaprevir/pibrentasvir, elbasvir/grazoprevir);
- some medicines used for angina (chest pain) or high blood pressure (e.g. diltiazem), medicines to regulate your heart rhythm (e.g. digoxin);
- medicine used in the treatment of other viral infections (cytomegalovirus) (e.g. letermovir);
- other medicines known to interact with ZARATOR include oral contraceptives, colchicine (used to

treat gout) and antacids (containing magnesium or aluminium for indigestion);
Consult your doctor if you get muscle weakness, tenderness or pain.

How to use ZARATOR

- 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 ZARATOR is 10 mg once a day in adults and children aged 10 or older. This may be increased if 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 ZARATOR is 80 mg once daily for adults and children with severe abnormal amount of lipids.

- When to use it

Use as directed by your doctor or pharmacist.

ZARATOR tablets should be swallowed whole with a glass of water, and can be taken at any time of day, with or without food. However, try to take your tablet at the same time every day.

- How long to use it

Continue taking ZARATOR 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 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 ZARATOR.

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

You should avoid alcohol while you are taking ZARATOR.

- 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 ZARATOR to anyone else, even if they have the same symptoms or condition as you.
- Do not take more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice can change the effects of ZARATOR.
- Do not drink too much alcohol while taking ZARATOR.

- 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, ZARATOR can cause side effects, although not everybody gets them.

If you experience any of the following serious side effects, stop taking your tablets and tell your doctor immediately or go to the nearest hospital's accident and emergency department.

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

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Frequent side effects:

- inflammation of the nasal passages;
- increase in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels);
- pain in the throat, nose bleed;
- 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 may be abnormal, increase in blood creatine phosphokinase (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, fever;
- urine tests that are positive for white blood cells.
- autoimmune disease presenting with weakness of the muscles close to the core of the body with cellular injury to the muscle cells but with minimal inflammation (immune-mediated necrotizing myopathy)

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 in 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, swelling of the area beneath the skin;
- muscle weakness, inflammation 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 (rhabdomyolysis), autoimmune disease presenting with weakness of the muscles close to the core of the body with cellular injury to the muscle cells but with minimal inflammation (immune-mediated necrotizing myopathy), inflammation of the muscles (myositis), back pain;
- chest pain, swelling especially in the ankles, fatigue
- cognitive impairment (e.g. memory loss/impairment, forgetfulness, amnesia, confusion);
- increase in blood sugar levels such as HbA1c (average blood sugar for two or three months) and fasting blood sugar.
- myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing);
- ocular myasthenia (a disease causing eye muscle weakness).
- abnormal skin reactions to sunlight or UV rays

Please 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.

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 ZARATOR

- Storage

Store below 30°C.

Keep out of the reach and sight of children.

- 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

Atorvastatin tablets for oral administration contain 10 mg, 20 mg, 40 mg or 80 mg crystalline atorvastatin.

10 mg: White, round, film-coated tablets debossed “10” on one side and “ATV” on the other side.

20 mg: White, round, film-coated tablets debossed “20” on one side and “ATV” on the other side.

40 mg: White, round, film-coated tablets debossed “40” on one side and “ATV” on the other side.

80 mg: White, round, film-coated tablets debossed “80” on one side and “ATV” on the other side.

Not all strengths are marketed

- Ingredients

- Active ingredient
Crystalline atorvastatin calcium.
- Inactive ingredients
Calcium carbonate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, polysorbate 80, hydroxypropyl cellulose, magnesium stearate, hydroxypropyl methylcellulose, polyethylene glycol 8000, titanium dioxide, talc, simethicone emulsion.

- MAL number

Product Name: Registration Number

ZARATOR 10 mg Film Coated Tablet
MAL10100166ARZ
ZARATOR 20 mg Film Coated Tablet
MAL10100167ARZ
ZARATOR 40 mg Film Coated Tablet
MAL10110007ARZ
ZARATOR 80 mg Film Coated Tablet
MAL10100165ARZ

Manufacturer

Viatri Pharmaceuticals LLC
KM 1.9, Road 689, Vega Baja, PR 00693
Puerto Rico, USA

Product Registration Holder

Mylan Healthcare Sdn. Bhd.
(a Viatri Company)
15-03 & 15-04, Level 15, Imazium,
No.8, Jalan SS 21/37, Damansara
Uptown,

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47400, Petaling Jaya, Selangor.

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