

PIL Title :ETURION
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References :10 mg, 20 mg, 40 mg and 80 mg Eturion film-coated tablets of Malaysia LPD Information for the user dated 23 December 2013
Reason : Update as per latest Malaysian LPD dated 23rd December 2013.

ETURION FILM-COATED TABLETS

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

What is in this leaflet

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What ETURION is used for

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

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

ETURION 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.

ETURION 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 fats 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 plaque, 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 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 ETURION works

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

Before you use ETURION

- When you must not use it

Do not take ETURION

- if you are hypersensitive (allergic) to ETURION 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.

- Pregnancy and lactation

- Do not take ETURION if you are pregnant, or if you are trying to become pregnant.
- Do not take ETURION if you are able to become pregnant unless you use reliable contraceptive measures.
- Do not take ETURION if you are breast-feeding.
- The safety of ETURION 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

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

- 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 ETURION 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:

- 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 ETURION include warfarin (which reduces blood clotting), oral contraceptives, cimetidine (used for heartburn and peptic ulcers), colchicine (used to treat gout) and antacids (containing magnesium or aluminium for indigestion).

How to use ETURION

- 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 ETURION 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 ETURION 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.

ETURION tablets should be swallowed whole with a drink 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 ETURION 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 ETURION.

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

You should avoid alcohol while you are taking ETURION.

- 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 ETURION 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 ETURION.
- Do not drink too much alcohol while taking ETURION.

- 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, ETURION 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.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumer→Reporting).

Storage and Disposal of ETURION**- 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, 20, 40 or 80 mg crystalline atorvastatin.
 10 mg: White, elliptical, film-coated tablets debossed “10” on one side and “PD 155” on the other side.
 20 mg: White, elliptical, film-coated tablets debossed “20” on one side and “PD 156” on the other side.
 40 mg: White, elliptical, film-coated tablets debossed “40” on one side and “PD 157” on the other side.
 80 mg: White, elliptical, film-coated tablets debossed “80” on one side and “PD 158” on the other side.

- Ingredients

- Active ingredient
 Crystalline atorvastatin calcium.

- Inactive ingredients

Calcium carbonate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, polysorbate 80, hydroxypropyl cellulose, magnesium stearate, opadry White YS-1-7040, simethicone emulsion, candellilla wax.

- MAL number**Product Name: Registration Number**

Eturion Tablet 10 mg MAL10100166AR
 Eturion Tablet 20 mg MAL10100167AR
 Eturion Tablet 40 mg MAL10110007AR
 Eturion Tablet 80 mg MAL10100165AR

Manufacturer & Product Registration Holder

Manufactured by:
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