

Cholestrom[®]

atorvastatin

BEST FRIEND OF YOUR HEART

Lowers cholesterol levels drastically
Prevents cardiovascular incidents

Reduces cardiovascular risk
Infarction, stroke & angina (chest pain)
Reduces cholesterol, LDL and triglycerides

INDICATIONS & POSOLOGY

Hypercholesterolemia	<p>The recommended starting dose is 10-20mg once daily.</p> <p>The maximum dose is 80mg once daily and is reserved for severe forms of the disease.</p> <p>The regime remains indispensable for the duration of the treatment.</p>
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DAFRA PHARMA INTERNATIONAL

Headquarters
Slachthuisstraat 30/7
2300 Turnhout – Belgium

3FICHOLE 2021

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Reduces cardiovascular risk
Infarction, stroke & angina (chest pain)

Reduces total cholesterol, LDL and triglycerides



Setting the standard

www.dafrapharma.com

Cholestrom®

atorvastatin

1. WHAT IS CHOLESTROM® AND WHAT IT IS USED FOR?

Cholestrom® belongs to a group of medicines known as statins (ATC code: C10A A05). Statins lower blood lipids such as cholesterol and triglycerides. Cholestrom® is advised when a low-fat diet and lifestyle changes have not been adequate to lower blood lipids as recommended. If you are at an increased risk of heart disease, Cholestrom® may also be used to reduce such risk even if your blood cholesterol is "normal". You should maintain a standard cholesterol-lowering diet during treatment.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CHOLESTROM®:

Do not take Cholestrom® if you are hypersensitive (allergic) to the active ingredient (atorvastatin) or to any similar medicine used to lower blood lipids or to any of the other ingredients of the medicine. If you have or have ever had a disease that affects the liver, if you have had any unexplained abnormal blood tests for liver function or if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Warnings and precautions

Talk to your doctor before taking Cholestrom® if you have or have had liver problems. If you have had a previous stroke with bleeding into the brain, or if you have fluid in the brain from previous stroke. If you have kidney problems. If you have severe respiratory failure. If you have an under-active thyroid gland (hypothyroidism). If you have had repeated or unexplained muscle aches or pains, a personal history or a family history of muscle problems. If you have had previous muscle problems during treatment with other lipid-lowering medicines (i.e. other 'statin' or 'fibrate' medicines). If you regularly drink a large amount of alcohol. If you have diabetes or are at risk of developing diabetes while you are on this medicine, your doctor will monitor you closely. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine (Cholestrom® contains lactose). If you are taking or have taken in the last 7 days a medicine called fusidic acid (a medicine for bacterial infection) orally or by injection: the combination of fusidic acid and Cholestrom® can lead to serious muscle problems (rhabdomyolysis). *The above are reasons why Cholestrom® may not be suitable for you:* if any of the above reasons apply to you, your doctor will need to carry out a blood test before and possibly during your treatment with Cholestrom®, especially to predict your risk of muscle related side effects. The risk of muscle related side effects e.g. rhabdomyolysis is known to increase when certain medicines are taken at the same time.

Other medicines and Cholestrom®

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Some medicines may change the effect of Cholestrom® or their effect may be changed by Cholestrom®. This type of interaction could make one or both of the medicines less effective. Alternatively it could increase the risk or severity of side-effects, including the important muscle wasting condition known as "rhabdomyolysis".

- **Fusidic acid:** taking Cholestrom® together with this medicine may rarely lead to muscle weakness, tenderness of pain (rhabdomyolysis). If you take oral fusidic acid to treat a bacterial infection you will need to temporarily stop Cholestrom®. Your doctor will tell you when it is safe to restart Cholestrom®.
- Medicines used to alter the way your immune system works e.g. cyclosporine.
- Certain antibiotics or antifungal medicines e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampin (used to treat bacterial infections).
- Other medicines to lower lipid levels e.g. gemfibrozil, other fibrates, colestipol.
- Medicines used for angina or high blood pressure known as "calcium channel blockers" e.g. amlodipine, diltiazem.
- Medicines to regulate your heart rhythm e.g. digoxin, verapamil, amiodarone.
- Medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, the combination of tipranavir/ritonavir etc.
- Some medicines used in the treatment of hepatitis C e.g. telaprevir.
- Other medicines known to interact with Cholestrom® include ezetimibe (lowers cholesterol), warfarin (reduces blood clotting), oral contraceptives, stiripentol (an anti-convulsant for epilepsy), cimetidine (used for heartburn and peptic ulcers), phenazone (a painkiller), colchicine (used to treat gout) and antacids (indigestion products containing aluminium or magnesium) and boceprevir (used to treat liver disease such as hepatitis C).
- Medicines obtained without a prescription e.g. St John's Wort.

Taking Cholestrom® with food and drink

- Grapefruit juice: 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 Cholestrom®.
- Alcohol: avoid drinking too much alcohol while taking this medicine.

Pregnancy, breast-feeding and fertility

Do not take Cholestrom® if you are pregnant, or if you are able to become pregnant unless you use reliable contraceptive measures, or if you are trying to become pregnant. Do not take Cholestrom® if you are breast-feeding.

Driving and using machines

Cholestrom® has negligible influence on the ability to drive and use machines.

3. HOW TO TAKE CHOLESTROM®

Always take it exactly as your doctor or pharmacist has told you. Before starting treatment, your doctor will advise a low-cholesterol diet: you should continue this diet whilst taking Cholestrom®. **The usual starting dose** of Cholestrom® is 10 mg once daily in adults and children aged 10 years 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 Cholestrom® is 80 mg once daily for adults and 20 mg once daily for children. Cholestrom® 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. **The duration of treatment** with Cholestrom® is determined by your doctor. **If you accidentally take more Cholestrom® than you should** (more than your usual daily dose) then contact your doctor or nearest hospital for advice. **If you forget to take Cholestrom®,** just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose. If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cholestrom® 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 emergency department: Inflammation of the pancreas causing abdominal pain and vomiting. Serious allergic reaction with swelling of the face, tongue, throat and windpipe that causing great difficulty in breathing. Sudden allergic reaction with shortness of breath, rash, wheezing and drop of blood pressure. Serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever, skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister. Unexpected or unusual bleeding or bruising. Report promptly to your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this. Severe muscle disease: muscle weakness, tenderness or pain and particularly if at the same time you also feel unwell or have a high temperature then the symptoms may be caused by abnormal muscle breakdown that can be life-threatening and lead to kidney problems. Other possible side effects with Cholestrom®: **Common side effects** (in up to 1 in 10 people): Inflammation and pain in the upper airways, pain in the throat, nose bleed. Headache. Nausea, constipation, wind, indigestion, diarrhoea. Joint pain, muscle pain and back pain. Allergic reactions. Increase

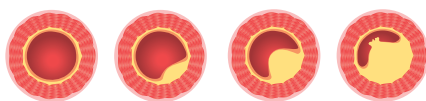
in blood sugar (if you have diabetes continue careful monitoring of your blood sugar levels), increase in blood creatine kinase, blood test of liver function can become abnormal. **Uncommon side effects** (in up to 1 in 100 people): Loss of appetite, weight gain, decreases in blood sugar levels, vomiting, belching, pain in upper and lower abdomen. Nightmares, sleeplessness, dizziness, ringing in the ears (tinnitus) and/or head. Numbness or tingling in the fingers and toes, reductions of sensation to pain or touch. Change in sense of taste. Loss of memory. Blurred vision. Liver inflammation. Skin rash, itching, hives, hair loss. Neck pain, chest pain, muscle fatigue. Fatigue, feeling unwell, weakness. Fluid retention causing swelling of the extremities, especially in the ankles (oedema). Fever. A urine test that gives a positive result for the presence of white bloodcells. **Rare side effects** (in up to 1 in 1 000 people): Visual disturbance. Unexpected bleeding or bruising, skin inflammation. Cholestasis (yellowing of the skin and whites of the eyes). Pain in muscle tendons that may rupture. **Very rare side effects** (in up to 1 in 10 000 people): Hearing loss. Increase in breast tissue in men. **Possible side effects reported with some statins** (medicines of the same type): Sexual difficulties. Depression. Breathing problems including persistent cough and/or shortness of breath or fever. Diabetes. *If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.*

5. HOW TO STORE CHOLESTROM®: Store below 25°C, in the original package, protected from humidity. Keep out of reach and sight of children. Do not use this medicine after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

6. OTHER INFORMATION: What Cholestrom® contains per film-coated tablet: Active Substance: 10 mg/20mg atorvastatin. Other ingredients: Tablet core: Activated attapulgite, Lactose monohydrate, Cellulose microcrystalline, Starch maize pregelatinised, Hydroxypropyl cellulose, Magnesium stearate, Silica Colloidal anhydrous. Film-coating: Titanium dioxide (E171), Lactose monohydrate, Macrogol, Hypromellose (E464). **Cholestrom® is presented** in a blister pack with 14 biconvex film-coated tablets; the breakline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Cholestrom® is sold with prescription only. DO NOT USE WITHOUT CONSULTING YOUR PHYSICIAN.

The deposit of cholesterol within the arterial wall leads to the formation of atherosclerotic plaques.



Atherosclerosis is the main cause of cardiovascular diseases.

For the complete SMPC, consult www.dafrapharma.com.