

## Patient Information Leaflet

### Cholestrom® 20

#### Atorvastatin 20 mg film-coated tablets

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. If you have questions or you notice side effects not mentioned in this leaflet, contact your doctor or your healthcare professional. Do not pass this medicine on to others.**

#### 1. What Cholestrom® is 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 allergic (hypersensitive) to atorvastatin or to any similar medicine used to lower blood lipids or to any other ingredient of this medicine listed in section 6.
- 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,
- if you are a woman able to have children and not using reliable contraception
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.
- if you use the combination of glecaprevir/pibrentasvir in the treatment of hepatitis C

##### 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 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).
- if you are older than 70 years

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 (see Section 2 "Other medicines and Cholestrom®").

Also tell 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.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

### **Other medicines and Cholestrom®**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines 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" described in Section 4.

- Fusidic acid: taking Cholestrom® together with this medicine may rarely lead to muscle weakness, tenderness of pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4. 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. ciclosporine.

- 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.
- Letemovir, a medicine that helps stop you from getting ill from cytomegalovirus
- 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, boceprevir and the combination of elbasvir/grazoprevir.
- 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).
- 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. See section 2 “Warnings and precautions” for details.

### **Pregnancy and breast-feeding**

If you think you might be pregnant, or are planning to get pregnant or if you are breast-feeding, you must tell your doctor that you are taking medicines.

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.

The safety of Cholestrom® during pregnancy and breast-feeding has not yet been proven. Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Normally this medicine does not affect your ability to drive or operate machines. However, do not drive if this medicine affects your ability to drive. Do not use any tools or machines if your ability to use them is affected by this medicine.

### **Important information about some ingredients of Cholestrom®20**

Cholestrom® 20 contains about 85 mg lactose monohydrate per tablet.

If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.

### **3. How to take Cholestrom®**

Always take Cholestrom® exactly as your doctor or health care provider 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 atorvastatin is 10 mg (Cholestrom®10) 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 atorvastatin is 80 mg (4 tablets Cholestrom® 20) once daily.

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. Please ask your doctor if you think that the effect of Cholestrom® is too strong or too weak.

#### **If you take Cholestrom® than you should**

If you accidentally take too many Cholestrom® tablets (more than your usual daily dose), contact your doctor or nearest hospital for advice.

#### **If you forget to take Cholestrom®**

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

#### **If you stop taking Cholestrom®**

Your doctor will advise you how long you should take this medicine.

If you have any further question on 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:**

Rare (may affect up to 1 in 1 000 people)

- Serious allergic reaction with swelling of the face, tongue, throat and windpipe that causing great difficulty in breathing.
- 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.
- Muscle weakness, tenderness, pain, rupture or red-brown discolouration of urine 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). The abnormal muscle breakdown does not always go away, even after you have stopped taking atorvastatin, and it can be life-threatening and lead to kidney problems.

Very rare (may affect up to 1 in 10 000 people)

- If you experience problems with unexpected or unusual bleeding or bruising, this may be suggestive of a liver complaint. You should consult your doctor as soon as possible.
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

**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 results that show your liver function can become abnormal

Uncommon side effects (in up to 1 in 100 people):

- Loss of appetite (anorexia), weight gain, decreases in blood sugar levels (if you have diabetes you should continue careful monitoring of your blood sugar levels).
- Vomiting, belching, pain in upper and lower abdomen, pancreatitis (inflammation of the pancreas leading to stomach pain).

- Nightmares, sleeplessness (insomnia).
- 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 (hepatitis).
- 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 blood cells.

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):

- An allergic reaction - symptoms may include sudden wheezing and chest pain or tightness, swelling of the eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse
- Hearing loss.
- Increase in breast tissue in men (gynecomastia).

Not known: frequency cannot be estimated from the available data:

- Muscle weakness that is constant.

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. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

**Reporting of side effects**

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or health care provider.

**5. How to store Cholestrom®20**

Keep out of the reach and sight of children.

Store below 25°C, in the original package to protect from moisture.

Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

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.

**6. Contents of the pack and further information****What Cholestrom®20 contains**

The active substance is 20 mg atorvastatin (as atorvastatin calcium).

The other ingredients are:

Tablet core: Activated attapulгите, Lactose monohydrate, Cellulose microcrystalline, Maize starch partially pregelatinised, Hydroxypropyl cellulose, Magnesium stearate, Silica Colloidal anhydrous.

Film-coating: Titanium dioxide (E171), Lactose monohydrate, Macrogol, Hypromellose (E464).

**What Cholestrom® 20 looks like and content of the pack**

Cholestrom®20 is presented in an Aluminum/Aluminium blister with 10 white, oval, biconvex film-coated tablets, having a breakline on one side to facilitate breaking for ease of swallowing. Box with 30 tablets.

**Cholestrom® 20** is a prescription medicine.

**Manufacturer**

Pharmathen SA, 6, Dervenakion str., 153 51 Pallini, Athens, Greece

**Marketing Authorisation Holder**

Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland.

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