Package leaflet: Information for the user

Torvacol 10mg Film-coated Tablets
Torvacol 20mg Film-coated Tablets
Torvacol 40mg Film-coated Tablets
Torvacol 80mg Film-coated Tablets

Atorvastatin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Torvacol is and what it is used for
Torvacol belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

Torvacol is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. If you are at an increased risk of heart disease, Torvacol can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.

2. What you need to know before you take Torvacol
DO NOT take Torvacol
- if you are allergic to atorvastatin or any of the other ingredients of this medicine (listed in section 6)
- 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

Warnings and precautions
Talk to your doctor or pharmacist before taking Torvacol
- Torvacolif you have severe respiratory failure
- 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 Torvacol can lead to serious muscle problems (rhabdomyolysis)
- 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 kidney problems
- if you have an under-active thyroid gland (hypothyroidism)
- 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 regularly drink a large amount of alcohol
- if you have a history of liver disease
- if you are older than 70 years

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your Torvacol treatment 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 Torvacol").

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.
Torvacol
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 Torvacol
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are some medicines that may change the effect of Torvacol or their effect may be changed by Torvacol. 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:
- Medicines used to alter the way your immune system works, e.g. ciclosporin
- Certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampin, fusidic acid
- TorvacolTorvacolOther medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol
- Some calcium channel blockers used for angina or high blood pressure, 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 Torvacol include ezetimibe (which lowers cholesterol), warfarin (which 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), antacids (indigestion products containing aluminium or magnesium) and boceprevir (used to treat liver disease such as hepatitis C)
- Medicines obtained without a prescription: St John's Wort
- If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart Torvacol. Taking Torvacol with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

Torvacol with food, drink and alcohol
See section 3 for instructions on how to take Torvacol. Please note the following:

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 Torvacol.

Alcohol
Avoid drinking too much alcohol while taking this medicine. See section 2 "Warnings and precautions" for details

Pregnancy and breast-feeding
Do not take Torvacol if you are pregnant, or if you are trying to become pregnant.

Do not take Torvacol if you are able to become pregnant unless you use reliable contraceptive measures.

Do not take Torvacol if you are breast-feeding.

The safety of Torvacol during pregnancy and breast-feeding has not yet been proven.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this 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.

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

3. How to take Torvacol
Before starting treatment, your doctor will place you on a low-cholesterol diet, which you should maintain also during therapy with Torvacol.

The recommended starting dose of Torvacol is 10 mg once a day 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 Torvacol is 80 mg once a day.

Torvacol 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.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Always take Torvacol exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The duration of treatment with Torvacol is determined by your doctor.

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

If you take more Torvacol than you should
If you accidently take too many Torvacol tablets (more than your usual daily dose), contact your doctor or nearest hospital for advice.

If you forget to take Torvacol
If you forget to take a dose, 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 stop taking Torvacol
If you have any further questions on the use of this medicine or wish to stop your treatment, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine 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 accident and emergency department.

Rare (may affect up to 1 in 1,000 people)
- Serious allergic reaction which causes swelling of the face, tongue and throat that can cause 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 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). 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.

Other possible side effects with Torvacol
Common (may affect up to 1 in 10 people)
- Inflammation of the nasal passages, pain in the throat, nose bleed.
- Allergic reactions.
- Increases in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels), increase in blood creatine kinase.
- Headache.
- Nausea, constipation, wind, indigestion, diarrhoea.
- Joint pain, muscle pain and back pain.
- Blood test results that show your liver function can become abnormal.

Uncommon (may affect up to 1 in 100 people)
- Anorexia (loss of appetite), weight gain, decreases in blood sugar levels (if you have diabetes you should continue careful monitoring of your blood sugar levels).
- Having nightmares, insomnia.
- Dizziness, 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.
- Ringing in the ears and/or head.
- Vomiting, belching, abdominal pain upper and lower, pancreatitis (inflammation of the pancreas leading to stomach pain).
- Hepatitis (liver inflammation).
- Rash, skin rash and itching, hives, hair loss.
- Neck pain, muscle fatigue.
- Fatigue, feeling unwell, weakness, chest pain, swelling especially in the ankles (oedema), raised temperature.
- Urine tests that are positive for white blood cells.

Rare (may affect up to 1 in 1,000 people)
- Visual disturbance.
- Unexpected bleeding or bruising.
- Cholestasis (yellowing of the skin and whites of the eyes).
- Tendon injury.

Very rare (may affect 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.
- Gynecomastia (breast enlargement in men).

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 you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Torvacol
Keep this medicine out of the sight and reach of children.

Do not store above 30 °C. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton label and blister foil after {EXP}. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information
What Torvacol contains
The active substance of Torvacol is atorvastatin.

Torvacol 10 mg film-coated tablets
Each tablet contains 10 mg of atorvastatin as atorvastatin calcium.

Torvacol 20 mg film-coated tablets
Each tablet contains 20 mg of atorvastatin as atorvastatin calcium.

Torvacol 40 mg film-coated tablets
Each tablet contains 40 mg of atorvastatin as atorvastatin calcium.

Torvacol 80 mg film-coated tablets
Each tablet contains 80 mg of atorvastatin as atorvastatin calcium.

Torvacol film-coated tablets also contain the other ingredients:
Lactose monohydrate,
Cellulose powdered
Hypromellose 6cp and 100cp
Meglumine
Sodium starch glycolate type A
Magnesium stearate

The coating of Torvacol film-coated tablets contains:
Hypromellose 6cp
Povidone 25 (K-25)
Titanium dioxide (E171)
Propylene glycol

What Torvacol looks like and contents of the pack
Torvacol 10 mg film-coated tablets are white to off-white, round and biconvex film-coated tablets scored on one side, with a diameter of approximately 7.6 mm. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
Torvacol 10 mg film-coated tablets are packed in OPA-Aluminium-PVC/Aluminium blister containing 10, 14, 28, 30, 50, 56, 84, 90, 98, 100 and 112 film-coated tablets.

Torvacol 20 mg film-coated tablets are white to off-white, oval and biconvex film-coated tablets with a score line on one side with a length of approximately 12.7 mm and a width of approximately 6.0 mm. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
Torvacol 20 mg film-coated tablets are packed in OPA-Aluminium-PVC/Aluminium blister containing 10, 14, 28, 30, 50, 56, 84, 90, 98, 100 and 112 film-coated tablets.

Torvacol 40 mg film-coated tablets are white to off-white, oval and biconvex film-coated tablets with a score line on one side with a length of approximately 16.3 mm and a width of approximately 7.7 mm. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
Torvacol 40 mg film-coated tablets are packed in OPA-Aluminium-PVC/Aluminium blister containing 10, 14, 28, 30, 50, 56, 84, 90, 98, 100 and 112 film-coated tablets.

Torvacol 80 mg film-coated tablets are white to off-white, oblong and biconvex film-coated tablets with score lines on both sides, with a length of approximately 21.1 mm and a width of approximately 9.1 mm. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
Torvacol 80 mg film-coated tablets are packed in OPA-Aluminium-PVC/Aluminium blister containing 10, 14, 28, 30, 50, 56, 98, 100 and 112 film-coated tablets.

Not all pack sizes may be marketed.

This medicine is available as 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets.

Marketing Authorisation Holder and Manufacturer

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland
STADA Arzneimittel AG, Stadastrasse 2–18, 61118 Bad Vilbel, Germany
LAMP SAN PROSPERO S.p.A., Via della Pace, 25/A, 41030 San Prospero (Modena), Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Atorvilbitin 10/20/40/80 mg Filmtabletten
Belgium:	Atorvastatine EG 10/20/40/80 mg filmomhulde tabletten
Bulgaria:	Atorvastatin AL 10/ 20 mg, филмирани таблетки
Denmark:	Atorvastatin STADA 10/20/40/80 mg filmovertrukne tabletter
Germany:	Atorvastatin STADA 10/20/40/80 mg Filmtabletten
Hungary:	Atorvastatin STADA 10/20/40 mg filmtabletta
Ireland:	Torvacol 10/20/40/80 mg film-coated tablets
Italy:	ATORVASTATINA EUROGENERICI 10 mg, 20 mg, 40 mg, 80 mg compresse rivestite con film
Luxemburg:	Atorvastatine EG 10/20/40/80 mg comprimés pelliculés
Portugal:	Atorvastatina Ciclum Farma
Romania:	Atorvilbitin 10/20/40 mg
Slovenia:	Atorvastatin STADA 10/20/40 mg filmsko obložene tablete

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