

Tovast[®]

TOVAST 10 mg film-coated tablets
TOVAST 20 mg film-coated tablets
TOVAST 40 mg film-coated tablets
Atorvastatin

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT TOVAST IS AND WHAT IT IS USED FOR
2. BEFORE YOU TAKE TOVAST
3. HOW TO TAKE TOVAST
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE TOVAST
6. FURTHER INFORMATION

1. WHAT TOVAST IS AND WHAT IT IS USED FOR

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

Tovast 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, Tovast 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. BEFORE YOU TAKE TOVAST

Do not take Tovast

- If you are hypersensitive (allergic) to Tovast or to any similar medicines used to lower blood lipids or to any of the other ingredients of the medicine – see Section 6 for details.
 - 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.
- Take special care with Tovast**
- The following are reasons why Tovast may not be suitable for you:
- 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.

All patients treated with Tovast should be advised to report promptly any symptoms that may indicate liver injury, including fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice.

Check with your doctor or pharmacist before taking Tovast

If you have severe respiratory failure.

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

Endocrine Function

While you are on this medicine your doctor will monitor you closely if you have diabetes or 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.

Increase in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including Tovast

Liver dysfunction

Liver function tests should be performed prior to and at 12 week following both the initiation of therapy and any elevation of dose, and periodically (e.g., semiannually) thereafter. Liver enzyme changes generally occur in the first 3 months of treatment with Tovast.

Taking other medicines

There are some medicines that may change the effect of Tovast or their effect may be changed by Tovast. 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:

1. 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.
2. Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol.
3. 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.
4. Medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, etc.
5. Some medicines used in the treatment of hepatitis C e.g. telaprevir.
6. Boceprevir (used to treat liver disease such as hepatitis C).
7. Other medicines known to interact with Tovast 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) and antacids (indigestion products containing aluminium or magnesium).
8. Medicines obtained without a prescription: St John's Wort.
9. Colchicine: Cases of myopathy, including rhabdomyolysis, have been reported with atorvastatin co-administered with colchicine, and caution should be exercised when prescribing atorvastatin with colchicine

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Tovast with food and drink

See Section 3 for instructions on how to take Tovast. 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 Tovast.

Alcohol

Avoid drinking too much alcohol while taking this medicine. See Section 2 "Take special care with Tovast" for details

Pregnancy and breast-feeding

Do not take Tovast if you are pregnant, or if you are trying to become pregnant. Do not take Tovast if you are able to become pregnant unless you use reliable contraceptive measures.

Do not take Tovast if you are breast-feeding.

The safety of Tovast 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 of the ingredients of Tovast

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

3. HOW TO TAKE TOVAST

Before starting treatment, your doctor will place you on a low-cholesterol diet, which you should maintain also during therapy with Tovast.

The usual starting dose of Tovast 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 Tovast is 80 mg once daily for adults and 20 mg once daily for children.

Tovast 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.

Always take Tovast exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

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

If you take more Tovast than you should

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

If you forget to take Tovast

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 Tovast

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, Tovast 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: affects 1 to 10 users in 10,000:

- 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 which can be life-threatening and lead to kidney problems.

Very rare: affect less than 1 user in 10,000:

- 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 Tovast:

Common side effects (affects 1 to 10 users in 100) include:

- 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 side effects (affects 1 to 10 users in 1000) include:

- 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 (edema), raised temperature.
- Urine tests that are positive for white blood cells.

Rare side effects (affects 1 to 10 users in 10,000) include:

- Visual disturbance.
- Unexpected bleeding or bruising.
- Cholestasis (yellowing of the skin and whites of the eyes).
- Tendon injury.

Very rare side effects (affect less than 1 user in 10,000) include:

- 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 and women).

Side effects of unknown frequency:

- 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.
- Increase in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including Tovast

The following additional side effects have been reported with Tovast:

Tiredness, tendon problems, memory loss, and confusion.

"There have been rare postmarketing reports of cognitive impairment (e.g., memory loss, forgetfulness, amnesia, memory impairment, confusion) associated with statin use. These cognitive issues have been reported for all statins. The reports are generally non-serious, and reversible upon statin discontinuation, with variable times to symptoms onset (1 day to years) and symptoms resolution (median of 3 weeks)".

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

5. HOW TO STORE TOVAST

Store below 30°C.

Keep out of the reach and sight of children.

This medicine does not require any special storage conditions.

Do not use Tovast after the expiry date which is stated on the container and outer packaging after (EXP).

6. FURTHER INFORMATION

What Tovast contains

The active substance is atorvastatin.

Each film-coated tablet contains 10 mg atorvastatin (as atorvastatin calcium trihydrate).

Each film-coated tablet contains 20 mg atorvastatin (as atorvastatin calcium trihydrate).

Each film-coated tablet contains 40 mg atorvastatin (as atorvastatin calcium trihydrate).

The other ingredients of Tovast are: calcium carbonate precipitated, lactose NF fast flow, croscarmellose sodium type A, magnesium stearate.

Film-Coating: Poly sorbate 80, titanium dioxide, purified talc, polyethylene glycol, hydroxypropyl methylcellulose.

What Tovast looks like and contents of the pack

Tovast 10mg - a white to off-white, oblong, biconvex film-coated tablet, engraved with "19" on one side and a plain on the other side.

Tovast 20mg - a white to off-white, oblong, biconvex film-coated tablet, engraved with "20" on one side and a plain on the other side.

Tovast 40mg - a white to off-white, oblong, biconvex film-coated tablet, engraved with "21" on one side and a plain on the other side.

Marketing Authorizations Holder and Manufacturer

Manufactured by **SPIMACO**

Al-Qassim Pharmaceutical Plant

Saudi Pharmaceutical Industries &

Medical Appliances Corporation.

Saudi Arabia

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"Tovast" is a trade mark
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To report any side effect(s):

- o The National Pharmacovigilance and Drug Safety Centre (NPC)
- o Fax: +966-11-205-7662
- o Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- o Toll free phone: 8002490000
- o E-mail: npc.drug@sfd.gov.sa
- o Website: www.sfd.gov.sa/npc

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medicament.
- The doctor and the pharmacists are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists