

Proprietary name:	ATORVASTATIN 10 mg, 20 mg, 40 mg, 80 mg ALKEM
Dosage form:	Film-coated tablet
Active Ingredient:	Atorvastatin calcium
Strength per dosage unit:	10 mg; 20 mg; 40 mg or 80 mg per tablet

1.3.2 PATIENT INFORMATION LEAFLET (FINAL)

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Atorvastatin 10 mg Alkem Film-coated Tablets

Atorvastatin 20 mg Alkem Film-coated Tablets

Atorvastatin 40 mg Alkem Film-coated Tablets

Atorvastatin 80 mg Alkem Film-coated Tablets

10 mg; 20 mg, 40 mg and 80 mg of atorvastatin (as calcium).

Contains Sugar.

Atorvastatin 10 mg/ 20 mg/ 40 mg/ 80 mg Alkem: Each film-coated tablet contains 31.25 mg/ 62.50 mg/ 125 mg/ 250 mg of lactose monohydrate.

Please read this leaflet carefully before taking Atorvastatin Alkem.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **Atorvastatin Alkem** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **Atorvastatin Alkem** is and what it is used for
2. What you need to know before you take **Atorvastatin Alkem**
3. How to take **Atorvastatin Alkem**

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4. Possible side effects
5. How to store **Atorvastatin Alkem**
6. Contents of the pack and other information

1. WHAT ATORVASTATIN ALKEM IS AND WHAT IT IS USED FOR

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

Atorvastatin Alkem 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, 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 ATORVASTATIN ALKEM

Do not take Atorvastatin Alkem:

- 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,
- if you use the combination of glecaprevir/pibrentasvir in the treatment of hepatitis C.

Do not take Atorvastatin Alkem, if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking **Atorvastatin Alkem**.

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Warnings and special precautions:

Take special care with Atorvastatin Alkem:

- if 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 **Atorvastatin Alkem** 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 in the last 6 months,
- 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.

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 **Atorvastatin Alkem**”).

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.

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Children and adolescents

Do not give **Atorvastatin Alkem** to children below the age of 10 years.

Using other medicines with Atorvastatin Alkem:

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 **Atorvastatin Alkem** or their effect may be changed by **Atorvastatin Alkem**. This type of interaction could make one or both medicines less effective.

Alternatively, it could increase the risk or severity of side-effects, including the important muscle wasting condition known as rhabdomyolysis:

- 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,
- other 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,
- medicines to regulate your heart rhythm, e.g., diltiazem, digoxin, verapamil, amiodarone,
- medicines that help stop you from getting ill from cytomegalovirus, e.g., letermovir,
- medicines used in the treatment of HIV, e.g., ritonavir, lopinavir, atazanavir, indinavir, darunavir, the combination of tipranavir/ritonavir etc.,

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- medicines used in the treatment of hepatitis C, e.g., telaprevir, boceprevir and the combination of elbasvir/grazoprevir,
- medicines known to interact with **Atorvastatin Alkem**, e.g., 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), and antacids (indigestion products containing aluminium or magnesium),
- herbal medicines obtained without a prescription: St John's Wort.

Your doctor will tell you when it is safe to restart taking **Atorvastatin Alkem**.

Atorvastatin Alkem with food and drink

Atorvastatin Alkem can be taken with or without food.

Grapefruit juice:

Do not take **Atorvastatin Alkem** with grapefruit juice and grapefruit containing foods, as grapefruit juice can change the effects of **Atorvastatin Alkem**.

Alcohol:

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

Pregnancy and Breastfeeding

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

Do not take **Atorvastatin Alkem** if you are breast-feeding.

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The safety of **Atorvastatin Alkem** 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

Atorvastatin Alkem can causes dizziness and blurry vision which can affect your ability to drive or use dangerous equipment. Do not drive or use any tools or machines if your ability is affected by this medicine.

Atorvastatin Alkem contains lactose monohydrate:

If you have been told by your doctor that you cannot tolerate some sugars, tell your doctor before taking **Atorvastatin Alkem**. This is because **Atorvastatin Alkem** contains lactose.

3. HOW TO TAKE ATORVASTATIN ALKEM

Do not share medicines prescribed for you with any other person.

Always take **Atorvastatin Alkem** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine:

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

The usual starting dose of **Atorvastatin Alkem** is 10 mg once a day in adults. 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 Alkem** is 80 mg once a day.

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Atorvastatin Alkem 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 duration of treatment with Atorvastatin Alkem is determined by your doctor.

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

If you take more Atorvastatin Alkem than you should:

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

If you forget to take Atorvastatin Alkem:

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 Atorvastatin Alkem:

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

Atorvastatin Alkem can have side effects.

Not all side effects reported for Atorvastatin Alkem are included in this leaflet. Should your general health worsen while taking **Atorvastatin Alkem** please consult your doctor, pharmacist, or other healthcare professional for advice.

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If any of the following happens, stop taking **Atorvastatin Alkem** and tell your doctor immediately or go to the casualty department at your nearest hospital:

Less frequent side -effects:

- 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, 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.
- 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).

These are all serious side effects. You may need urgent medical attention. Tell your doctor if you notice any of the following:

Frequent side-effects:

- inflammation of the nasal passages, pain in the throat, nosebleed,
- 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,

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- nausea, constipation, wind, indigestion and diarrhoea,
- joint pain, muscle pain and back pain,
- blood test results that show your liver function can become abnormal.

Less frequent side-effects:

- 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, and insomnia.
- dizziness, numbness or tingling in the fingers and toes, reductions of sensation to pain or touch, change in sense of taste and loss of memory.
- blurred vision.
- ringing in the ears and/or head.
- vomiting, belching, abdominal pain upper and lower and pancreatitis (inflammation of the pancreas leading to stomach pain).
- hepatitis (liver inflammation).
- rash, skin rash and itching, hives and hair loss.
- neck pain and muscle fatigue.
- fatigue, feeling unwell, weakness, chest pain, swelling especially in the ankles (oedema) and raised temperature.
- urine tests that are positive for white blood cells.
- visual disturbance.
- unexpected bleeding or bruising.
- cholestasis (yellowing of the skin and whites of the eyes).
- tendon injury.

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- 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 and collapse.
- hearing loss.
- gynecomastia (breast enlargement in men).

Frequency unknown:

- 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **Atorvastatin Alkem**. Alternatively, all adverse events can be reported to Ascend Laboratories via the e-mail: pharmacist.rsa@Alkem.com.

5. HOW TO STORE ATORVASTATIN ALKEM

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Store at or below 25 °C.

Do not remove blister from carton until required for use. Keep bottle tightly closed. Store in the original package in order to protect from moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton, the blister and the bottle.

Do not throw away any medicines in drains or sewage systems.

Return all unused medicine to the pharmacist.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

The active ingredient is atorvastatin (as calcium).

Atorvastatin 10 mg Alkem: Each film-coated tablet contains atorvastatin calcium equivalent to atorvastatin 10 mg.

Atorvastatin 20 mg Alkem: Each film-coated tablet contains atorvastatin calcium equivalent to atorvastatin 20 mg.

Atorvastatin 40 mg Alkem: Each film-coated tablet contains atorvastatin calcium equivalent to atorvastatin 40 mg.

Atorvastatin 80 mg Alkem: Each film-coated tablet contains atorvastatin calcium equivalent to atorvastatin 80 mg.

Other ingredients are calcium carbonate, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, polysorbate 80 and coating material (Opadry White YS-1-7040).

The coating material is made up of hypromellose, macrogol, talc and titanium dioxide.

What Atorvastatin Alkem looks like and contents of the pack:

Atorvastatin 10 mg Alkem: White elliptical shaped, film-coated tablets, debossed with "10" on one side and "ATS" on other side.

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Atorvastatin 20 mg Alkem: White elliptical shaped, film-coated tablets, debossed with “20” on one side and "ATS" on other side.

Atorvastatin 40 mg Alkem: White elliptical shaped, film-coated tablets, debossed with “40” on one side and "ATS" on other side.

Atorvastatin 80 mg Alkem: White elliptical shaped, film-coated tablets, debossed with “80” on one side and "ATS" on other side.

Contents of the pack:

Atorvastatin Alkem are packed in aluminium-aluminium blister packs containing 10 tablets per blister, which is inserted into an outer container. **Atorvastatin Alkem** is also packed in white, opaque, round HDPE bottles enclosed with a child resistant or non-child resistant cap with a desiccant inside. The bottles contain 90 or 500 tablets.

Holder of certificate of registration

Ascend Laboratories (Pty) Ltd.

R21 Corporate Park,

121 Sovereign Drive, Block A, Office 202

Irene Ext. 30, Centurion, 0157

This leaflet was last revised in

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Application Numbers:

Atorvastatin 10 mg Alkem: 550608

Atorvastatin 20 mg Alkem: 550609

Atorvastatin 40 mg Alkem: 550610

Atorvastatin 80 mg Alkem: 550611

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Access to the corresponding Professional Information

The professional information will be included in each unit pack of the product.