

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

XALIPMIN 10 (film-coated tablets)

XALIPMIN 20 (film-coated tablets)

XALIPMIN 40 (film-coated tablets)

XALIPMIN 80 (film-coated tablets)

XALIPMIN 10: Each film-coated tablet contains atorvastatin calcium trihydrate, equivalent to 10 mg atorvastatin

XALIPMIN 20: Each film-coated tablet contains atorvastatin calcium trihydrate, equivalent to 20 mg atorvastatin

XALIPMIN 40: Each film-coated tablet contains atorvastatin calcium trihydrate, equivalent to 40 mg atorvastatin

XALIPMIN 80: Each film-coated tablet contains atorvastatin calcium trihydrate, equivalent to 80 mg atorvastatin

Contains sugar: mannitol.

Read all of this leaflet carefully before you start taking XALIPMIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- XALIPMIN 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 XALIPMIN is and what it is used for
2. What you need to know before you take XALIPMIN
3. How to take XALIPMIN
4. Possible side effects
5. How to store XALIPMIN
6. Contents of the pack and other information

1. What XALIPMIN is and what it is used for

XALIPMIN contains a medicine called atorvastatin which belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

XALIPMIN lowers cholesterol in your blood. It lowers the LDL-C (bad cholesterol) and triglycerides in your blood. It can raise your HDL-C (good cholesterol) as well. XALIPMIN is for adults and children older than 10 years whose cholesterol does not come down enough with exercise and a low-fat diet alone.

XALIPMIN can lower risk of heart disease and disorders of the blood vessels of the brain, which are conditions due to reduced blood supply, in patients who have multiple risk factors for heart disease, such as smoking, hypertension, diabetes, low HDL-C, or a family history of early coronary heart disease.

XALIPMIN can reduce heart events in patients with heart disease and high cholesterol levels.

2. What you need to know before you take XALIPMIN

Do not take XALIPMIN

- if you are hypersensitive (allergic) to atorvastatin or any of the other ingredients of XALIPMIN (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 use the combination of glecaprevir/pibrentasvir in the treatment of hepatitis C.
- 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 are taking rifampicin an antibiotic for infection
- if you take diltiazem, a calcium channel blocker, for angina or high blood pressure
- if you drink grapefruit juice

Warnings and precautions

Take special care with XALIPMIN:

- if you have a chronic autoimmune disease that causes weakness in the skeletal muscle or the muscles that affect movement of the eye and eyelids
- 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 XALIPMIN 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 interstitial lung disease (a group of lung disorders in which the lung tissues becomes inflamed and then damaged)
- if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other 'statins' or 'fibrate' medicines)

- if you regularly drink a large amount of alcohol and/or 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 XALIPMIN 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 XALIPMIN”). 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.

Children and adolescents

Do not give XALIPMIN to children below the age of 10 years.

Other medicines and XALIPMIN

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines).

There are some medicines that may change the effect of XALIPMIN or their effect may be changed by XALIPMIN. 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 “Possible side effects”:

- 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, rifampicin, fusidic acid.
- Other medicines to lower cholesterol 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. atazanavir, indinavir, saquinavir plus ritonavir, lopinavir plus ritonavir, tipranavir plus ritonavir, darunavir plus ritonavir, fosamprenavir and fosamprenavir plus ritonavir
- 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 XALIPMIN include:
 - ezetimibe (lowers cholesterol),
 - warfarin (reduces blood clotting),
 - oral contraceptives,
 - stiripentol (an anti-convulsant for epilepsy), colchicine (used to treat gout)
 - antacids (indigestion products containing aluminium or magnesium)
 - medicines obtained without a prescription such as St John’s Wort

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- 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 XALIPMIN. Taking XALIPMIN with fusidic acid may lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

XALIPMIN with food and drink

You can take XALIPMIN with or without food. Avoid grapefruit juice and large quantities of alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not take XALIPMIN if you are pregnant, or if you are trying to become pregnant.

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

Do not take XALIPMIN if you are breast-feeding.

The safety of XALIPMIN during pregnancy and breastfeeding has not yet been proven.

Driving and using machines

Normally XALIPMIN 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.

XALIPMIN contains mannitol

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 XALIPMIN

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

Always take XALIPMIN exactly as your doctor has told you.

Your doctor will decide on the appropriate dose of XALIPMIN, depending on your condition and whether you are taking other medicines.

The usual starting dose of XALIPMIN is 10 mg once a day. 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 XALIPMIN is 80 mg once a day.

XALIPMIN 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.

Remember to continue with your diet and lifestyle changes while you are taking XALIPMIN.

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

If you take more XALIPMIN than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take XALIPMIN

If you miss a dose of XALIPMIN, take it as soon as you remember, unless it is time to take the next dose. Do not take 2 doses at the same time to make up for the forgotten dose.

4. Possible side effects

XALIPMIN can have side effects.

Not all side effects reported for XALIPMIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking XALIPMIN, please consult your health care provider for advice.

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

Less frequent:

- Serious allergic reaction which causes swelling of the face, tongue and throat that can cause great difficulty in breathing or swallowing.
- Rash or itching

These are all very serious side effects. If you have them, you may have had a serious reaction to XALIPMIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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 or rupture, 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. The abnormal muscle breakdown does not always go away, even after you

have stopped taking atorvastatin 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;
- 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:

- 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

Less frequent:

- 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
- 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
- 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)

Frequency not known:

- Muscle weakness that is constant
- Myasthenia gravis (chronic autoimmune disease that causes weakness in the skeletal muscle)
- Ocular myasthenia (weakness in the muscles that affect movement of the eye and eyelids)

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, 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 XALIPMIN.

5. How to store XALIPMIN

- Store all medicines out of reach of children.
- Store at or below 25 °C
- Store in the original package/ container
- Do not use after the expiry date stated on the label and carton
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What XALIPMIN contains

- The active substance is atorvastatin.

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

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

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

Each 80mg tablet contains 80 mg atorvastatin (as atorvastatin calcium trihydrate).

- The other ingredients are:

Tablet Core

Trinity Pharma (Pty) Ltd.

Application name (number): Xalipmin 10/20/40/80 (490477-480)

Mannitol, sodium lauryl sulfate, ethanol, colloidal anhydrous silica, anhydrous sodium carbonate, butylhydroxyanisole, microcrystalline cellulose, croscarmellose sodium, magnesium stearate and purified water.

Tablet Film Coating

Sepifilm LP 010 (containing hypromellose, microcrystalline cellulose and stearic acid), purified water.

What XALIPMIN looks like and contents of the pack

The tablets are available in Alu-Alu blister [Aluminium Foil of cold form blister (Lidding foil) and Cold form laminate for Alu Alu blister (Forming foil)] as 28 or 30 tablets.

Holder of Certificate of Registration

Trinity Pharma (Pty) Ltd

106 16th Road

Building 2, Midrand

South Africa

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Xalipmin 20: 49/7.5/0478

Xalipmin 40: 49/7.5/0479

Xalipmin 80: 49/7.5/0480

Trinity Pharma (Pty) Ltd.

Application name (number): Xalipmin 10/20/40/80 (490477-480)

Access to the corresponding Professional Information

For Professional Information (PI) refer to our website:

<http://www.trinitypharma.co.za/disclaimer>