

PATIENT INFORMATION LEAFLET**Scheduling status**

S4

LIPINORM 10 mg film-coated tablets**LIPINORM 20 mg** film-coated tablets**LIPINORM 40 mg** film-coated tablets**LIPINORM 80 mg** film-coated tablets

Atorvastatin calcium equivalent to atorvastatin

LIPINORM 10 mg: Each tablet contains lactose monohydrate 33 mg per tablet.

LIPINORM 20 mg: Each tablet contains lactose monohydrate 66 mg per tablet.

LIPINORM 40 mg: Each tablet contains lactose monohydrate 132 mg per tablet.

LIPINORM 80 mg: Each tablet contains lactose monohydrate 264 mg per tablet.

Read all of this leaflet carefully before you take LIPINORM

- 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.
- LIPINORM 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 LIPINORM is and what it is used for
2. What you need to know before you take LIPINORM
3. How to take LIPINORM
4. Possible side effects
5. How to store LIPINORM

6. Contents of the pack and other information

1. What LIPINORM is and what it is used for

LIPINORM contains a medicine called atorvastatin which belongs to a group of medicines known as lipid or cholesterol (fat) regulating medicines commonly known as statins.

LIPINORM 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. LIPINORM is for adults and children older than 10 years whose cholesterol does not come down enough with exercise and a low-fat diet alone.

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

2. What you need to know before you take LIPINORM

Do not take LIPINORM:

- if you are hypersensitive (allergic) to atorvastatin or any of the other ingredients of LIPINORM (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 breastfeeding.
- 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 LIPINORM:

- 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 LIPINORM 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 LIPINORM 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 LIPINORM'). 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 LIPINORM to children below the age of 10 years.

Other medicines and LIPINORM

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 LIPINORM or their effect may be changed by LIPINORM. 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 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. 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 atorvastatin include:
 - ezetimibe (which lowers cholesterol)
 - warfarin (which reduces blood clotting)
 - oral contraceptives
 - stiripentol (an anti-convulsant for epilepsy)
 - colchicine (used to treat gout)
 - antacids (indigestion medicines containing aluminium or magnesium) and
 - 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 LIPINORM. Your doctor will tell you when it is safe to restart LIPINORM. Taking LIPINORM with fusidic acid may lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

LIPINORM with food and drink

You can take LIPINORM 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 LIPINORM.

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

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

Do not take LIPINORM if you are breastfeeding.

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

Driving and using machines

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

LIPINORM contains lactose

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

3. How to take LIPINORM

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

Always take LIPINORM tablets exactly as your doctor has instructed you.

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

The usual starting dose is 10 mg once a day. Your doctor may increase the dose, if necessary until you are taking the correct amount required. The maximum dose is 80 mg once a day.

LIPINORM tablets can be taken at any time of the 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 LIPINORM.

If you have the impression that LIPINORM is too strong or too weak, talk to your doctor or pharmacist.

If you take more LIPINORM than you should

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

If you forget to take LIPINORM

If you miss a dose of LIPINORM, 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

LIPINORM can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to LIPINORM. 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 (oedema), 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
- an allergic reaction - symptoms may include sudden wheezing and chest pain
- tightness, swelling of the eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse
- hearing loss
- gynecomastia (breast enlargement in men).

Frequency not known

- muscle weakness that is constant.

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: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of LIPINORM.

5. How to store LIPINORM

Store all medicines out of reach of children.

Store at or below 30 °C. Keep blisters in the carton until required for use.

Do not store in a bathroom.

Do not use LIPINORM after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What LIPINORM contains

The active substance is atorvastatin calcium. Each film-coated tablet contains atorvastatin calcium equivalent to 10 mg, 20 mg, 40 mg or 80 mg atorvastatin.

The other ingredients are microcrystalline cellulose (Avicel PH 101), lactose, calcium carbonate, croscarmellose sodium, polysorbate 80, hydroxypropyl cellulose, magnesium stearate, colour Opadry white.

What LIPINORM looks like and contents of the pack

LIPINORM 10 mg: White to off white, oval, biconvex, film-coated tablets plain on both sides.

LIPINORM 20 mg: White to off white, oval, biconvex, film-coated tablets plain on both sides.

LIPINORM 40 mg: White to off white, oval, biconvex, film-coated tablets plain on both sides.

LIPINORM 80 mg: White to off white, oval, biconvex, film-coated tablets plain on both sides.

The film-coated tablets are packed in Aluminium/Aluminium foil blister strips. The blister strips are packed in cartons containing 28 or 30 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Smart Pharmaceuticals (Pty) Ltd

247 Voortrekker Road

Kraaifontein, Cape Town

7570

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