

CLEAN AMENDED PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ALIPTO 10, 10 mg film-coated tablets, (Atorvastatin)

ALIPTO 20, 20 mg film-coated tablets, (Atorvastatin)

ALIPTO 40, 40 mg film-coated tablets, (Atorvastatin)

ALIPTO 80, 80 mg film-coated tablets, (Atorvastatin)

ALIPTO 10 contains sugar (mannitol 70,97 mg/tablet) and 2,93 mg of sodium per tablet.

ALIPTO 20 contains sugar (mannitol 141,94 mg/tablet) and 5,86 mg of sodium per tablet.

ALIPTO 40 contains sugar (mannitol 283,88 mg/tablet) and 11,72 mg of sodium per tablet.

ALIPTO 80 contains sugar (mannitol 567,76 mg/tablet) and 23,44 mg of sodium per tablet.

Read all of this leaflet carefully before you start taking ALIPTO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ALIPTO** 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 **ALIPTO** is and what it is used for.
2. What you need to know before you take **ALIPTO**.
3. How to take **ALIPTO**.
4. Possible side effects.

5. How to store **ALIPTO**.

6. Contents of the pack and other information.

1. What ALIPTO is and what it is used for

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

ALIPTO 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, **ALIPTO** 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 ALIPTO

Do not take ALIPTO:

- if you are hypersensitive (allergic) to atorvastatin or any of the other ingredients of **ALIPTO**,
- if you have or had a disease which affects the liver,
- if you have had any unexplained abnormal blood tests for liver function,
- if you are taking medication for tuberculosis, high blood pressure, heart pain or any other heart condition,
- if you take grapefruit juice,
- if you are a women of child bearing age and not using reliable contraception,
- if you are pregnant or planning to become pregnant,
- if you are breastfeeding.

Warnings and special precautions

Tell your doctor or healthcare professional before being given **ALIPTO**:

- if you have had a previous stroke with bleeding into the brain, or have small pockets or have small pockets of fluid in the brain from previous strokes,
- if you have a history of liver disease,
- if you have a history of kidney disease,
- if you have a history of heart failure, heart attack or any other form of heart disease,
- 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 are elderly (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 **ALIPTO** treatment to predict your risk of muscle related side effects.

Talk to your doctor before taking **ALIPTO** if you have diabetes. There have been reports of an increase in glycosylated haemoglobin (a situation where glucose becomes stuck to haemoglobin) and an increase in fasting blood sugar levels when taking **ALIPTO**. This could be a sign or indication that your diabetes is not well controlled.

There is a risk of myasthenia gravis and ocular myasthenia with taking **ALIPTO**.

Children and Adolescents: For use in children, take **ALIPTO** only if you are between the ages of 10 – 17 years. Do not take more than 20 mg per day.

Other medicines and ALIPTO

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- 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. ritonavir, lopinavir, atazanavir, indinavir, darunavir, etc.
- other medicines known to interact with **ALIPTO** 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)
- medicines obtained without a prescription: St John's Wort.
- ticagrelor, a medicine used to prevent blood clotting, as this may cause the concentration of **ALIPTO** to increase.

Taking ALIPTO with food and drink

Grapefruit juice

Do not take grapefruit juice because it can change the effects of **ALIPTO**.

Alcohol

Avoid drinking too much alcohol while taking **ALIPTO**.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding while taking **ALIPTO**, please consult your doctor, pharmacist or other health care professional for advice.

Do not take **ALIPTO** if you are pregnant, or if you are planning to become pregnant.

Women of child-bearing age should use appropriate contraceptive measures during treatment with **ALIPTO**.

Do not take **ALIPTO** if you are breastfeeding.

Driving and using machinery

ALIPTO may cause dizziness, headache, blurred vision and visual disturbances. Do not use any tools or machines or drive if your ability is affected by **ALIPTO**.

ALIPTO contains mannitol, which may have a mild laxative effect or cause diarrhoea.

ALIPTO 10/ 20/ 40: This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

ALIPTO 80: This medicinal product contains 23,44 mg sodium per tablet equivalent to 1,17 % of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO TAKE ALIPTO

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

Always take **ALIPTO** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

1. The usual starting dose of **ALIPTO** is 10 mg once a day in adults and children aged 10 – 17 years old. 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 **ALIPTO** is 80 mg once daily for adults and 20 mg once daily for children aged 10 – 17 years old.
2. Take tablets whole and swallow with a sufficient quantity of water, and take at any time of the day, with or without food. However, try to take your tablet at about the same time every day.
3. Your doctor will tell you how long your treatment with **ALIPTO** will last.
4. If you have the impression that the effect of **ALIPTO** is too strong or too weak, tell your doctor or pharmacist.

If you take more ALIPTO than you should:

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

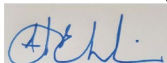
If you forget to take ALIPTO:

Try to take **ALIPTO** as prescribed. However, 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.

4. Possible side effects

ALIPTO can have side effects.

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



healthcare professional for advice.

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

- 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,
- problems with unexpected or unusual bleeding or bruising, this may be suggestive of a liver problem. You should consult your doctor as soon as possible.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ALIPTO**. 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:

- chest pain,
- swelling below the skin surface that may affect any part of the body including the eyes, hands, feet, genitals and mouth,
- difficulty breathing,
- redness and swelling of the passages in the nose, pain in the throat, nose bleeding,
- joint pain, muscle pain and back pain.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- nasopharyngitis (sore, inflamed throat),
- reductions of sensation to pain or touch, dizziness, headache,
- nausea (feeling sick), diarrhoea, abdominal pain or stomach cramps, indigestion, constipation, flatulence or wind,
- itching and rash,
- muscle pain, pain in a joint or joints, back pain,
- weakness or lack of energy.

Less frequent:

- if your blood takes longer to clot, you may have a lower than normal number of white blood cells and platelets in the blood,
- low or high blood sugar (ask your doctor how often you should have your blood tested and what tests you need to have done), weight loss, weight gain,
- nightmares, difficulty in sleeping, partial or total loss of memory, forgetfulness, confusion,
- numbness or tingling in the fingers and toes, change in sense of taste,
- blurred vision,
- ringing in the ears and/or head, hearing loss,
- nausea and vomiting, belching, upper and lower stomach pain, pancreatitis (inflammation of the pancreas leading to stomach pain),
- inflammation of the liver (you may feel sick, tired, have dark urine, unusually light coloured stools, yellowing of the skin and whites of the eyes), liver failure (you may feel

sick, tired, have diarrhoea and a swollen stomach),

- loss of hair, hives, skin rash, itching,
- inflammation of the muscle tissue, muscle weakness, muscle cramps, neck pain, tendon injury,
- gynaecomastia (breast enlargement in men and women),
- impotence (inability to have an erection),
- weakness, swelling especially in the ankles (oedema), tiredness, raised temperature.

Frequency unknown:

- Myasthenia gravis
- Ocular myasthenia

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. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>.

Report all side effects to Unimed Healthcare (Pty) Ltd.

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

5. How to store ALIPTO

- Store all medicines out of the reach of children.
- Store at or below 25 °C.

- Protect from moisture.
- Keep the blisters in the outer carton until required for use.
- Do not use after the expiry date stated on the carton.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

WHAT ALIPTO contains

The active substance in **ALIPTO** is atorvastatin.

ALIPTO 10:

Each film-coated tablet-contains atorvastatin calcium trihydrate equivalent to 10 mg atorvastatin.

ALIPTO 20:

Each film-coated tablet-contains atorvastatin calcium trihydrate equivalent to 20 mg atorvastatin.

ALIPTO 40:

Each film-coated tablet-contains atorvastatin calcium trihydrate equivalent to 40 mg atorvastatin.

ALIPTO 80:

Each film-coated tablet contains atorvastatin calcium trihydrate equivalent to 80 mg atorvastatin.

The other ingredients are anhydrous sodium carbonate, butylated Hydroxyanisole (antioxidant), colloidal anhydrous silica, croscarmellose sodium, mannitol (sugar), microcrystalline cellulose, septifilm LP 010 (hypromellose, microcrystalline cellulose and stearic acid) and sodium lauryl sulphate.

What ALIPTO looks like and contents of the pack

Film-coated tablets.

ALIPTO 10: White coloured, oval shaped, biconvex film coated tablets with one side embossed "10" and other side plain.

ALIPTO 20: White coloured, oval shaped, biconvex film coated tablets with one side embossed "20" and other side plain.

ALIPTO 40: White coloured, oval shaped, biconvex film coated tablets with one side embossed "40" and other side plain.

ALIPTO 80: White coloured, oval shaped, biconvex film coated tablets with one side embossed "80" and other side plain.

Blisters: Alu-Alu blister composed of silver opaque Alu-Alu cold form laminate & silver opaque Aluminium foil containing 7 tablets or 10 tablets.

Cartons containing 28 tablets (4 x 7's) or 30 tablets (3 x 10's).

Holder of certificate of registration

Unimed Healthcare (Pty) Ltd

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South Africa

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