

Approved Proposed Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

LIPOGEN 10 (Film coated tablets)

LIPOGEN 20 (Film coated tablets)

LIPOGEN 40 (Film coated tablets)

LIPOGEN 80 (Film coated tablets)

Atorvastatin

Contains sugar: lactose anhydrous.

LIPOGEN 10: lactose anhydrous 35, 36 mg

LIPOGEN 20: lactose anhydrous 76,69 mg

LIPOGEN 40: lactose anhydrous 153,38 mg

LIPOGEN 80 : lactose anhydrous 306,76 mg

Read all of this leaflet carefully before you start taking LIPOGEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or healthcare provider.
- **LIPOGEN** 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 **LIPOGEN** is and what it is used for

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2. What you need to know before you take **LIPOGEN**

3. How to take **LIPOGEN**

4. Possible side effects

5. How to store **LIPOGEN**

6. Contents of the pack and other information to take **LIPOGEN**

1. What LIPOGEN is and what it is used for.

LIPOGEN tablets are used to lower fats known as cholesterol and triglycerides in your blood when a low fat diet and other non-medicinal treatments such as exercise and life style changes have failed. You should maintain a standard cholesterol lowering diet during treatment.

LIPOGEN 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.

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

2. What you need to know before you take LIPOGEN

Do not take **LIPOGEN** tablets if:

- you have previously had an allergic reaction to atorvastatin or to any of the tablet ingredients of **LIPOGEN** listed in section 6 (an allergic reaction may include rash, itching, swelling of face, lips, or hands/feet or breathing difficulties)
- you have a liver disease (symptoms may indicate fatigue, loss of appetite, right upper abdominal discomfort, dark urine, or jaundice – yellow discolouration of the skin)
- you have any unexplained abnormal blood test results for liver function
- you are pregnant, or planning to become pregnant (see also **Pregnancy, breastfeeding and fertility**)

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- you are breastfeeding
- you are taking rifampicin (used to treat tuberculosis), diltiazem (used to treat chest pain or high blood pressure) and grapefruit juice at the same time.

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

Warnings and precautions

Take special care with LIPOGEN tablets if:

- you have kidney problems or a history of kidney problems
- you have or have had repeated or unexplained muscle pains or cramps, muscle tenderness, weakness particularly if accompanied by fever
- you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. simvastatin, fenofibrate classes of medicines)
- you consume substantial quantities of alcohol and/or have a history of liver disease. Your doctor may perform some blood tests called liver function tests
- you are an elderly patient
- you have severe acute infection, low blood pressure, major surgery, trauma, diseases of metabolism (e.g. diabetes) or hormonal diseases or electrolytes disorders (abnormalities in the blood levels of sodium, potassium), or uncontrolled seizures (fits)
- you have a disease of low thyroid levels
- you have had a previous stroke with bleeding into the brain
- you have serious problems with your breathing (Interstitial lung disease) with symptoms including shortness of breath, persistent cough and deterioration in general health (fatigue, weight loss and fever).

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Please consult your doctor if these statements are applicable or were applicable to you any time in the past or if you are not sure if these are applicable to you.

Laboratory tests

Your doctor may carry out a few blood tests before and possibly during your **LIPOGEN** treatment.

LIPOGEN contains lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus.

While you are on **LIPOGEN**, your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes.

LIPOGEN should be taken with caution if you have been told by your doctor that you have an intolerance to lactose. Contact your doctor before taking **LIPOGEN**.

Taking LIPOGEN tablets with food and drink:

LIPOGEN tablets can be taken any time of the day, with or without food.

LIPOGEN must not be taken with grapefruit juice.

Alcohol: Avoid drinking too much alcohol while taking **LIPOGEN** (see Section “**Take special care with LIPOGEN**” for details).

Other medicines and LIPOGEN:

Always tell your healthcare provider 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:

It is especially important to tell your doctor if you are taking:

- medicines used to alter the way your immune system works (e.g. ciclosporin)
- medicines used to treat certain bacterial or fungal infections [e.g. macrolide antibiotics (e.g. erythromycin, telithromycin, clarithromycin, azithromycin); rifampicin; azole antifungals (e.g. ketoconazole, fluconazole, itraconazole, voriconazole, posaconazole, clotrimazole); fusidic acid]

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- medicines used to regulate lipid levels (e.g. gemfibrozil, fenofibrate, other fibrates, ezetimibe, niacin/nicotinic acid, nicotinic acid derivatives, colestipol, cholestyramine)
- medicines used to treat chest pain (angina) or high blood pressure (e.g. amlodipine, diltiazem, verapamil)
- medicines used to regulate your heart rhythm (e.g. digoxin, amiodarone)
- medicine used to treat high blood pressure and certain types of swelling (e.g. spironolactone)
- medicines used for the treatment of HIV infection (e.g. delavirdine, efavirenz, HIV protease inhibitors like lopinavir, darunavir, tipranavir plus ritonavir, lopinavir plus ritonavir, saquinavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, fosamprenavir plus ritonavir; nelfinavir, atazanvir, indinavir)
- medicine used for the treatment of hepatitis C (e.g. hepatitis C protease inhibitor like telaprevir, boceprevir, elbasvir/grazoprevir)
- medicines used as blood thinning agents (e.g. warfarin/ other anticoagulants)
- medicines used for indigestion [e.g. antacid (containing magnesium and aluminium hydroxides), cimetidine]
- hormonal contraceptive pills [e.g. birth controlling pills (norethindrone + ethinyl estradiol)]
- medicine used to treat joint pain (e.g. colchicine)
- medicine used to treat fever and pain (e.g. antipyrene/ phenazone)
- a herbal medicine for treating mild forms of depression: St John's Wort
- medicine used to treat epilepsy (e.g. stiripentol)
- medicines used for high blood pressure and hormone (oestrogen) replacement medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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Pregnancy

Do not take **LIPOGEN** if you are pregnant, or planning to become pregnant, or are breastfeeding your baby.

Women of child bearing age should use adequate contraceptive measures while taking **LIPOGEN**.

If you are trying to become pregnant your doctor will advise you to stop taking **LIPOGEN** about one month before you plan to conceive.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **LIPOGEN**

Breast-feeding

LIPOGEN must not be used during breast-feeding.

Fertility

No data available.

Driving and using machinery:

LIPOGEN may cause dizziness and blurred vision which can impair your ability to drive or use machinery.

Do not drive if **LIPOGEN** affects your ability to drive. Do not use any tools or machines if your ability to use them is affected by **LIPOGEN**.

3. How to take **LIPOGEN**:

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

Make sure you continue with your recommended diet, exercise and other lifestyle changes while on **LIPOGEN**.

Always take **LIPOGEN** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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LIPOGEN tablets should be swallowed whole with a drink or 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.

Adults and elderly patients

The usual starting dose of **LIPOGEN** tablets is 10 mg once a day. This may be increased if deemed necessary by your doctor. Your doctor will adjust the dosage at intervals of 4 weeks or more. The maximum dose of **LIPOGEN** is 80 mg once daily.

Children (> 10 to 17 years of age)

The usual starting dose of **LIPOGEN** tablets is 10 mg once a day. The maximum dose of **LIPOGEN** is 20 mg once daily.

LIPOGEN tablets are not recommended in patients below the age of 10 years.

The duration of treatment with **LIPOGEN** tablets will be determined by your doctor.

*If you have the impression that the effect of **LIPOGEN** tablets is too strong or too weak, talk to your doctor or pharmacist.*

If you take more LIPOGEN 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. Take this leaflet or some tablets with you so your doctor will know what you have taken.

If you forget to take a dose of LIPOGEN:

If you forget to take **LIPOGEN** at the right time, take them as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

LIPOGEN can have side effects.

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Not all side effects reported for **LIPOGEN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **LIPOGEN**, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- sudden signs of allergic (hypersensitivity) reactions or allergy, which may manifest as an itchy skin rash [including severe skin rash (bullous rash)], hives, chest constriction, shortness of breath, breathing problems, wheezing or 'swelling of face, lips, eyelids, throat or tongue, hands/feet (angioedema)', loss of circulation (anaphylactic reaction), high temperature (these may be symptoms of a serious allergic reaction),
- detachment of the top layer of skin (the epidermis) from the lower layers of the skin (the dermis) all over the body (including lips, eyes, mouth, nose and genitals) known as toxic epidermal necrolysis,
- a serious skin disorder which begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters, eventually causing the top layer of the skin to die and shed (Stevens-Johnson Syndrome),
- a skin disorder with symptoms of fever, general ill feeling, itching of the skin, joint aches and multiple skin lesions (erythema multiforme),
- 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 (rhabdomyolysis and myopathy),

Contact your doctor immediately if you experience pain, soreness or weakness in your muscles, especially if in conjunction with feeling unwell or feverish, as treatment with LIPOGEN tablets may need to be discontinued or the dose reduced.

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- collapse, numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech. These may be symptoms of stroke/ haemorrhagic stroke (damage to part of the brain caused by an interruption to its blood supply).

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

- sudden onset of severe abdominal pain with vomiting,
- yellowing of skin and whites of eyes with decreased appetite, abdominal pain.

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

Tell your doctor if you notice any of the following:

Frequent:

- diarrhoea (loose stools), constipation, nausea (feeling sick), indigestion, winds,
- headache,
- muscle cramps, muscle and joint pains, back pain,
- high sugar (glucose) levels in the blood with symptoms such as passing large amounts of urine, excessive thirst and having a dry mouth and skin,
- swelling of hands, ankles or feet,
- inflammation of muscles, muscle cramps/spasms,
- sore throat, sinusitis, throat pain,
- muscle tiredness,
- nose bleed.

Less frequent:

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- difficulty in sleeping,
- vomiting (being sick), loss of appetite, abdominal pain,
- weakness,
- skin rash, itching, hair loss,
- dizziness,
- pins and needles sensation, burning, tingling sensation, pain in hands/feet,
- ringing of the ears,
- weight gain,
- chest pain,
- generally feeling unwell,
- reduction in blood platelets, which increases risk of bleeding or bruising,
- low sugar (glucose) levels in the blood with symptoms such as sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heart beat,
- numbness or weakness of the arms and legs (peripheral neuropathy), loss of memory, taste disturbances,
- tiredness,
- pain and weakness in muscles,
- fever,
- neck pain, joint swelling,
- frightening dreams,
- vision problems/disturbance, vision blurred, hearing loss,
- enlarged breasts in men,
- skin disease with blisters,
- pain in legs or arms.

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The following side effects have been reported but the frequency is unknown:

- urinary tract infection,
- abdominal discomfort,
- muscle and bone pain,
- depression, memory loss/impairment, confusion, forgetfulness,
- sexual inability or difficulties,
- diabetes,
- a disorder that results in progressive scarring of lung tissue that eventually affects the ability to breathe and get enough oxygen into the bloodstream (interstitial lung disease).

There may be changes in the results of certain laboratory tests:

- increased blood levels of liver enzymes,
- increased blood alkaline phosphatase,
- elevated creatine phosphokinase,
- decrease in platelet count (a type of blood cells),
- white blood cells in urine,
- increase in blood HbA1c and change in blood glucose.

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. This includes any possible side effects not listed in this leaflet. 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 **LIPOGEN**.

5. How to store LIPOGEN

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Store at or below 25 °C in the original package, protected from light and moisture.

Do not remove the blisters from the carton until required for use.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What LIPOGEN contains

The active substance is:

Atorvastatin calcium equivalent to atorvastatin.

The other ingredients are:

Lactose monohydrate 38,34 mg / 10 mg tablet

Lactose monohydrate 76,70 mg / 20 mg tablet

Lactose monohydrate 153,40 mg / 40 mg tablet

Lactose monohydrate 306,80 mg / 80 mg tablet

Butylated hydroxy anisole as antioxidant

Butylated hydroxy toluene as antioxidant

Colloidal anhydrous silica

Croscarmellose sodium

Hydroxy propyl cellulose-L

Isopropyl alcohol

Magnesium stearate

Microcrystalline cellulose

Sodium carbonate anhydrous

Sodium lauryl sulphate

Film coating ingredients:

Opadry YS-1-7040 white

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Hypromellose 6 cp

Macrogol / PEG 8000

Titanium dioxide

Talc

Purified water

What LIPOGEN looks like and contents of the pack

LIPOGEN 10:

White to off-white, film coated, oval shaped tablets debossed with 'A30' on one side and plain on the other side with intact coating.

LIPOGEN 20

White to off-white, film coated, oval shaped tablets imprinted with 'A31' on one side and plain on the other side with intact coating.

LIPOGEN 40

White to off-white, film coated, oval shaped tablets imprinted with 'A32' on one side and plain on the other side with intact coating.

LIPOGEN 80

White to off-white, film coated, oval shaped tablets imprinted with 'A33' on one side and plain on the other side with intact coating.

LIPOGEN tablets are packed in cartons containing 30 tablets packed in cold form blister strips of 10 tablets each. Cold form blister strips comprise of cold form blister laminate composed of aluminium foil (one side bright, soft tempered, plain; dull side lacquer laminated to oriented polyamide film; bright side lacquer laminated to PVC film), PVC and polyamide with a backing of aluminium foil coated with heat seal lacquer on the inner side.

Holder of Certificate of Registration

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LIPOGEN 20: 42/7.5/0557

LIPOGEN 40: 42/7.5/0558

LIPOGEN 80: 42/7.5/0559

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website

Namibia: NS2

LIPOGEN 10 : 19/7.5/0087

LIPOGEN 20 : 19/7.5/0088

LIPOGEN 40: 19/7.5/0089

LIPOGEN 80 : 19/7.5/0090

Botswana: S2

LIPOGEN 10 : BOT1703032

LIPOGEN 20 : BOT1703033

LIPOGEN 40: BOT1703034

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LIPOGEN 80 : BOT1703035

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