Approved 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 monohydrate
LIPOGEN 10: lactose monohydrate 38, 35 mg
LIPOGEN 20: lactose monohydrate 76,69 mg
LIPOGEN 40: lactose monohydrate 153,38 mg
LIPOGEN 80: lactose monohydrate 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
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**)
- 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).
- LIPOGEN can cause myasthenia gravis (muscle weaknes and fatigue) and ocular myasthenia (affects muscles that controls the eye movement).

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]
- 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. antipyrine/ 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.

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 ot 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.
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.
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.
- 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:

- 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.

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).
- Myasthenia gravis (muscle weakness and fatigue)
- Ocular myasthenia (weakened muscles that controls the eye movement).

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

- increased blood levels of liver enzymes,
- increased blood alkaline phosphatise,
- 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

Store at or below 25 ºC 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 38,35 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
Magnesium stearate
Microcrystalline cellulose
Sodium carbonate anhydrous
Sodium hydrogrn carbonate
Film coating ingredients:

Opadry YS-1-7040 white

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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Namibia: **NS2**
LIPOGEN 10 : 19/7.5/0087
LIPOGEN 20 : 19/7.5/0088
LIPOGEN 40: 19/7.5/0089
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Botswana: **S2**
LIPOGEN 10 : BOT1703032
LIPOGEN 20 : BOT1703033
LIPOGEN 40: BOT1703034
LIPOGEN 80: BOT1703035

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS:
S4

LIPOGEN 10 (Filmbedekte tablette)
LIPOGEN 20 (Filmbedekte tablette)
LIPOGEN 40 (Filmbedekte tablette)
LIPOGEN 80 (Filmbedekte tablette)
Atorvastatien
Bevat suiker: laktosemonohidraat
LIPOGEN 10: 38,34 mg laktosemonohidraat
LIPOGEN 20: 76,69 mg laktosemonohidraat
LIPOGEN 40: 153,38 mg laktosemonohidraat
LIPOGEN 80: 306,76 mg laktosemonohidraat

Lees die hele inligtingblad noukeurig deur voordat jy begin om LIPOGEN te neem

- Hou hierdie inligtingsblad. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of gesondheidsorgverskaffer as jy verdere vrae het.
- LIPOGEN is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander persone te deel nie. Dit kan skadelik vir hulle wees, selfs as hulle simptome dieselfde as joune is.

Wat is in hierdie inligtingsblad

1. Wat LIPOGEN is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy LIPOGEN neem
3. Hoe om LIPOGEN te neem
4. Moontlike newe-effekte
5. Hoe om LIPOGEN te bewaar
6. Inhoud van die pakkie en ander inligting oor hoe om LIPOGEN te neem

1. Wat LIPOGEN is en waarvoor dit gebruik word.

LIPOGEN tablette word gebruik om vette bekend as cholesterol en trigliseriede in jou bloed te verlaag wanneer ‘n lae-vet dieet en ander nie-medisinale behandelings soos oefening en lewensstylveranderinge gefaal het. Jy moet met ‘n standaard cholesterol-verlagende dieet volhou gedurende behandeling.
LIPOGEN kan die risiko van hartsiekte en versteurings van die bloedvate van die brein verlaag, wat toestande is as gevolg van verminderde bloedvoorsiening by pasiënte wat veelvuldige risikofaktore besit vir hartsiektes, soos rook, hoë bloeddruk, suikersiekte, lae HDL-C, of ‘n familiegeskiedenis van vroeë koronêre hartsiekte.
LIPOGEN kan hartvoorvalle by pasiënte wat hartsiekte en hoë cholesterolvlakke het, verlaag.

2. Wat jy moet weet voordat jy LIPOGEN neem

Moenie LIPOGEN tablette neem nie, as:

- jy voorheen ‘n allergiese reaksie teen atorvastatien of teen enige van die tabletbestanddele van LIPOGEN soos gelys onder afdeling 6 gehad het (‘n allergiese reaksie kan uitslag, gejeuk, swelling van die gesig, lippe of hande/voete of asemhalingsprobleme insluit)
- jy ‘n lewersiekte het (simptome kan dui op moegheid, verlies aan eetlus, regter boonste abdominale ongemak, donker urine, of geelsug - geel verkleuring van die vel)
- jy enige onverklaarbare abnormale bloedtoetsresultate vir lewerfunksie het

- jy swanger is, of beplan om swanger te raak (sien ook **Swangerskap, borsvoeding en vrugbaarheid**)
- jy borsvoed
- jy rifampisien (gebruik om tuberkulose te behandel), diltiasem (gebruik om borspyn of hoë bloeddruk te behandel) en pomelosap op dieselfde tyd neem.

Moenie LIPOGEN neem as enige van bogenoemde op jou van toepassing is nie. As jy nie seker is nie, praat asseblief met jou dokter of apteker voordat jy LIPOGEN neem.

Waarskuwings en voorsorgmaatreëls

Tref spesiale voorsorg met LIPOGEN tablette as:

- jy nierprobleme of ‘n geskiedenis van nierprobleme het
- jy herhaalde of onverklaarbare spierpyne of krampe, spierteerheid, swakheid, veral as dit gepaard gaan met koors, het of gehad het
- jy vorige spierprobleme tydens behandeling met ander lipied-verlagende middels gehad het (bv. simvastatien-, fenofibraat-medisyneklasse)
- jy aansienlike hoeveelhede alkohol gebruik en/of ‘n geskiedenis van lewersiekte het. Jou dokter kan sommige bloedtoetse uitvoer wat lewerfunksietoetse genoem word
- jy ‘n bejaarde pasiënt is
- jy erge akute infeksie, lae bloeddruk, major chirurgie, trauma, siektes van metabolisme (bv. diabetes) of hormonale siektes of elektrolietversteurings (abnormaliteite in die natrium-, kaliumbloedvlakke), of ongekontrolleerde stuipe (aanvalle) het
- jy ‘n siekte met lae tiroïedvlakke het
- jy ‘n vorige beroerte met bloeding op die brein gehad het
- jy ernstige asemhalingsprobleme het (interstisiële longsiekte) met simptome wat kortasemigheid, hardnekkige hoes en verswakking van die algemene gesondheid (moegheid, gewigsverlies en koors) insluit.

Raadpleeg asseblief jou dokter as hierdie stellings op jou van toepassing is of op enige stadium in die verlede op jou van toepassing was of as jy nie seker is of dit op jou van toepassing is nie.

Laboratoriumtoetse

Jou dokter mag ‘n paar bloedtoetse vóór en moontlik gedurende jou LIPOGEN-behandeling uitvoer.

LIPOGEN bevat laktosemonohidraat wat ‘n effek op die kontrolering van jou bloedsuiker mag hê as jy diabetes mellitus het.

Terwyl jy LIPOGEN, gebruik, sal jou dokter jou noukeurig dophou as jy diabetes het, of die risiko besit om diabetes te ontwikkel.

LIPOGEN moet met sorg geneem word as jou dokter jou ingelig het dat jy ‘n onverdraagsaamheid teenoor laktose het. Raadpleeg jou dokter voordat jy LIPOGEN neem.

Neem van LIPOGEN tablette saam met voedsel en drinkgoed:

LIPOGEN tablette kan enige tyd van die dag, met of sonder voedsel geneem word.

LIPOGEN moet nie saam met pomelosap geneem word nie**.**

Alkohol: Vermy dit om te veel alkohol te drink terwyl jy LIPOGEN neem (sien Afdeling “**Tref spesiale voorsorg met LIPOGEN**” vir besonderhede).

Ander medisyne en LIPOGEN:

Lig jou gesondheidsorgverskaffer altyd in as jy ander medisyne gebruik (dit sluit komplementêre of tradisionele medisyne in).

Lig jou dokter in as jy enige van die volgende medisyne gebruik:

Dit is veral belangrik om jou dokter in te lig as jy die volgende neem:

- medisyne wat gebruik word om die werking van jou immuunstelsel te verander (bv. siklosporien)
- medisyne wat gebruik word om sekere bakteriële of fungusinfeksies te behandel [bv. makroliedantibiotika (bv. eritromisien, telitromisien, klaritromisien, asitromisien);

rifampisien; asoolantifungusmiddels (bv. ketokonasool, flukonasool, itrakonasool, vorikonasool, posakonasool, klotrimasool); fusidiese suur]
- medisyne wat gebruik word om lipiedvlakke te reguleer (bv. gemfibrosiel, fenofibraat, ander fibrate, esetimieb, niasien/nikotiensuur, derivate van nikotiensuur, kolestipol, cholestiramien)
- medisyne wat gebruik word om borskaspyn (angina) of hoë bloeddruk te behandel (bv. amlodipien, diltiasem, verapamiel)
- medisyne wat gebruik word om hartritme te reguleer (bv. digoksien, amiodaroon)
- medisyne wat gebruik word om hoë bloeddruk en sekere tipes swelling te behandel (bv. spironolaktoon)
- medisyne wat gebruik word om MIV-infeksie te behandel (bv. delavirdien, efavirens, MIV protease-inhibeerders soos lopinavir, darunavir, tipranavir plus ritonavir, lopinavir plus ritonavir, sakwinavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, fosamprenavir plus ritonavir; nelfinavir, atasanvir, indinavir)
- medisyne wat gebruik word om hepatitis-C te behandel (bv. hepatitis-C protease-inhibeerders soos telaprevir, boseprevir, elbasvir/grasoprevir)
- medisyne wat gebruik word as bloedverdunningsmiddels (bv. warfarien/ander antikoagulante)
- medisyne wat gebruik word vir slegte spysvertering [bv. teensuurmiddels (bevattende magnesium- en aluminiumhidroksied), simetidien]
- hormonale voorbehoedingstablette [bv. geboortebeperkingstablette (noretindroon + etinielestradiol)]
- medisyne wat gebruik word om gewrigspyn te behandel (bv. kolgisien)
- medisyne wat gebruik word om koors en pyn te behandel (bv. antipirien/fenasoon)
- ‘n kruiemiddel wat gebruik word om ligte vorme van depressie te behandel: Johanneskruid (St John’s wort)
- medisyne wat gebruik word om epilepsie te behandel (bv. stiripentol)
- medisyne wat gebruik word vir hoë bloeddruk en hormoonvervangingsmedisyne (estrogeen).

Swangerskap, borsvoeding en vrugbaarheid
As jy swanger is of borsvoed, dink dat jy swanger mag wees of beplan om ‘n baba te hê, raadpleeg jou dokter of apteker vir advies voordat jy hierdie medisyne neem.

Swangerskap
Moenie LIPOGEN neem as jy swanger is, of beplan om swanger te raak, of as jy jou baba borsvoed nie.
Vroue van vrugbare ouderdom moet voldoende voorbehoedmaatreëls te tref terwyl hulle LIPOGEN gebruik.
As jy probeer om swanger te raak, sal jou dokter jou aanraai om die neem van LIPOGEN omtrent een maand voordat jy beplan om swanger te raak, te staak.
Raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgdeskundige vir advies voordat jy LIPOGEN neem as jy swanger is of jou baba borsvoed.

Borsvoeding
LIPOGEN moet nie tydens borsvoeding geneem word nie.

Vrugbaarheid
Geen data beskikbaar nie.

Bestuur en gebruik van masjinerie:
LIPOGEN kan duiseligheid en dowwe visie veroorsaak wat jou vermoë om te bestuur of masjinerie te hanteer, kan belemmer.
Moenie bestuur of enige gereedskap of masjiene gebruik as LIPOGEN jou visie of konsentrasie beïnvloed nie

3. Hoe om LIPOGEN te neem:

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Maak seker dat jy voortgaan met jou aanbevole dieet, oefening en ander lewensstylveranderinge terwyl jy LIPOGEN gebruik.
Neem LIPOGEN altyd presies soos wat dit deur jou dokter of apteker voorgeskryf is. Jy moet met jou dokter of apteker bevestig as jy onseker is.
LIPOGEN tablette moet heel met 'n drankie of water ingesluk word, en kan enige tyd van die dag, met of sonder voedsel, geneem word. Probeer egter om jou tablet elke dag op dieselfde tyd te neem.

Volwassenes en bejaarde pasiënte

Die normale aanvangsdosis van LIPOGEN tablette is 10 mg een keer per dag. Dit mag verhoog word indien jou dokter dit nodig ag. Jou dokter sal die dosering aanpas met intervalle van 4 weke of langer. Die maksimum dosis van LIPOGEN is 80 mg een keer per dag.

Kinders (ouderdom > 10 tot 17 jaar)

Die normale aanvangsdosis van LIPOGEN tablette is 10 mg een keer per dag. Die maksimum dosis van LIPOGEN is 20 mg een keer per dag.
LIPOGEN tablette word nie by pasiënte onder die ouderdom van 10 jaar aanbeveel nie.
Die duur van behandeling met LIPOGEN tablette sal deur jou dokter bepaal word.
Praat met jou dokter of apteker as jy onder die indruk is dat die effek van LIPOGEN tablette te sterk of te swak vir jou is.

As jy meer LIPOGEN geneem het as wat jy behoort te neem:

Raadpleeg jou dokter of apteker in die geval van oordosering. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Neem hierdie inligtingsblad of sommige tablette saam met jou sodat jou dokter kan weet wat jy geneem het.

As jy vergeet het om 'n LIPOGEN dosis te neem:

As jy vergeet het om jou LIPOGEN op die regte tyd te neem, neem dit sodra jy onthou. As dit egter amper tyd vir jou volgende dosis is, slaan die dosis oor wat jy vergeet het en gaan terug na die normale dosisskedule. Moenie 'n dubbele dosis neem om op te maak vir die individuele dosisse wat jy vergeet het nie.

4. Moontlike newe-effekte

LIPOGEN kan newe-effekte hê.
Nie alle newe-effekte wat vir LIPOGEN aangemeld word, is in hierdie inligtingsblad ingesluit nie.
Raadpleeg asseblief met jou dokter, apteker of ander professionele gesondheidsorgdeskundige vir advies indien jou algemene gesondheid verswak of as jy enige ongewenste effekte ondervind terwyl jy LIPOGEN neem.

As enige van die volgende gebeur, staak die gebruik van LIPOGEN en lig jou dokter dadelik in of gaan na die noodgevalle afdeling by jou naaste hospitaal:

- skielike tekens van allergiese (hipersensitiwiteits-) reaksies of allergie, wat as 'n jeukerige veluitslag [insluitende erge veluitslag (blaserige uitslag)], netelroos, borskaskonstriksie, kortasemigheid, asemhalingsprobleme, asemgefluit of 'swelling van die gesig, lippe, ooglede, keel of tong, hande/voete (angio-edeem)', sirkulasieverlies (anafilaktiese reaksie), hoë temperatuur (hierdie kan simptome van 'n ernstige allergiese reaksie wees) kan manifesteer,
- loslating van die boonste laag van die vel (die epidermis) vanaf die onderste lae van die vel (die dermis) oor die hele liggaam (insluitend lippe, oë, mond, neus en geslagsdele) bekend as toksiese epidermale nekrolise,
- 'n ernstige velafwyking wat begin met griepagtige simptome, gevolg deur 'n pynlike rooi of perskleurige uitslag wat versprei en blasies vorm, wat uiteindelik veroorsaak dat die boonste laag van die vel afsterf en verwerp word (Stevens-Johnson se Sindroom),
- 'n velafwyking met simptome van koors, algehele siek-gevoel, jeukende vel, gewrigspyne en veelvuldige velletsels (veelvuldige eriteem),
- spierswakheid, teerheid of pyn, en veral as jy tegelykertyd nie goed voel nie of 'n hoë koors het; dit mag deur 'n abnormale spierafbraak veroorsaak wees wat lewensbedreigend kan wees en lei tot nierprobleme (rabdomiolise en miopatie).

Raadpleeg jou dokter onmiddellik as jy pyn, seerheid of swakheid in jou spiere ervaar, veral as dit tesame met 'n siekerige gevoel of koors gepaard gaan, aangesien dit nodig mag wees om behandeling met LIPOGEN te staak of die dosis te verlaag.

- floute, dooie gevoel of swakheid van die arms of bene, hoofpyn, duiseligheid en verwardheid, gesigsversteuring, probleme om te sluk, sleepspraak en verlies van spraak ervaar. Hierdie mag simptome van beroerte/hemorragiese beroerte (skade aan 'n deel van die brein veroorsaak deur 'n onderbreking van die bloedvloei na die deel van die brein) wees.

Hierdie is almal baie ernstige newe-effekte. Jy mag 'n ernstige reaksie teenoor LIPOGEN gehad het as jy dit het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- skielike aanvang van erge abdominale pyn met braking,
- vergeling van die vel en wit van die oë met afname in aptyt, abdominale pyn.

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag benodig.

Lig jou dokter in as jy enige van die volgende opmerk:

Dikwels:

- diarree (los stoelgang), hardlywigheid, naarheid (mislike gevoel), slegte spysvertering, winderigheid,
- hoofpyn,
- spierkrampe, spier- en gewrigspyne, rugpyn,
- hoë suikervlakke (glukosevlakke) in die bloed met simptome soos passering van groot hoeveelhede urine, uitermatige dors en 'n droë mond en vel,
- swelling van hande, enkels of voete
- inflammasie van spiere, spierkrampe/spasmas,
- seerkeel, sinusitis, keelpyn,
- spiertamheid,
- neusbloeding.

Minder dikwels:

- sukkel om te slaap,
- braking (opgooi), verlies van aptyt, abdominale pyn,
- swakheid,
- veluitslag, gejeuk, haarverlies,
- duiseligheid,
- naalde en spelde sensasie, branderige, tintelende sensasie, pyn in hande/voete,
- gesuis in die ore,
- gewigstoename,
- borskaspyn,
- algemene siekerige gevoel,
- afname in bloedplaatjies, wat die risiko van bloeding of kneusing verhoog,
- lae suikervlakke (glukosevlakke) in die bloed met simptome soos sweet, swakheid, honger, duiseligheid, bewerigheid, hoofpyn, blosing of bleekheid, dooie gevoel, 'n vinnige, dreunende hartklop hê,
- dooie gevoel of swakheid van die arms en bene (perifere neuropatie), geheueverlies, smaakversteurings,
- moegheid,
- pyn en swakheid in spiere,
- koors,
- nekpyn, swelling van gewrigte,
- skrikwekkende drome,
- sigprobleme/versteuring, belemmerde sig, gehoorverlies,
- vergrote borste by mans,
- velsiekte met blasies,

- pyn in bene of arms.

Die volgende new-effekte is aangemeld, maar die voorkoms is onbekend:

- urienweginfeksie,
- abdominale ongemak,
- spier- en beenpyn,
- depressie, geheueverlies/inkorting, verwarring, vergeetagtigheid,
- seksuele onvermoë of probleme,
- diabetes,
- ‘n wanfunksie wat progressiewe littekens op longweefsel tot gevolg het en uiteindelik die vermoë om asem te haal en genoeg suurstof in die bloedstroom te verkry, affekteer (interstisiële longsiekte).

Daar mag veranderinge in die resultate van sekere laboratoriumtoetse wees:

- verhoogde bloedvlakke van lewerensieme,
- verhoogde alkaliese fosfatase in bloed,
- verhoogde kreatienfosfokinase,
- verminderde plaatjietelling (‘n tipe bloedsel),
- witbloedselle in urine,
- verhoging in bloed-HbA1c en verandering in bloedglukose.

As jy enige newe-effek opmerk, wat nie in hierdie inligtingsblad genoem word nie, moet jy asseblief jou dokter of apteker inlig.

Aanmelding van newe-effekte

Praat met jou dokter, apteker of verpleegster in as jy newe-effekte ervaar. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingsblad genoem word nie. Jy kan ook newe-effekte aanmeld by SAHPRA *via* die “6.04 Adverse Drug Reaction Reporting Form”, wat aanlyn beskikbaar is onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan jy help om meer inligting te verskaf oor die veiligheid van **LIPOGEN**.

5. Hoe om LIPOGEN te bewaar

Bewaar by of onder 25 °C in die oorspronklike verpakking, beskerm teen lig en vog.
Moenie die stulpstroke uit die kartonhouer verwyder totdat dit benodig word vir gebruik nie.
Moenie na die vervaldatum, soos op die etiket aangedui, gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker toe.
Moenie van ongebruikte medisyne in dreinering- of rioleringstelsels bv. toilette ontslae raak nie.

6. Inhoud van die pakkie en ander inligting

Wat LIPOGEN bevat

Die aktiewe bestanddeel is:
Kalsiumtrihidraatatorvastatien gelyk aan atorvastatien.
Die ander bestanddele is:
Laktosemonohidraat 38,34 mg / 10 mg tablet
Laktosemonohidraat 76,70 mg / 20 mg tablet
Laktosemonohidraat 153,40 mg / 40 mg tablet
Laktosemonohidraat 306,80 mg / 80 mg tablet
Gebutileerde hidroski-anisool as antioksidant
Gebutileerde hidroksi-tolueen as antioksidant
Kolloïdale anhidriese silika
Natriumkroskarmellose
Hidroksipropielsellulose-L
Isopropielalkohol
Magnesiumstearaat
Mikrokristallyne sellulose
Anhidriese natriumkarbonaat
Natriumlourielsulfaat

Filmbedekkingsbestanddele:
Opadry YS-1-7040 wit
Hipromellose 6 cp
Makrogol / PEG 8000
Titaniumdioksied
Talk
Gesuiwerde water

Hoe LIPOGEN lyk en inhoud van die verpakking
LIPOGEN 10:
Wit tot naaswit, filmbedekte, ovaalvormige tablette met 'A 30' ingedruk op die een kant en glad aan die ander kant met intakte filmbedekking.
LIPOGEN 20:
Wit tot naaswit, filmbedekte, ovaalvormige tablette met 'A 31' ingedruk op die een kant en

glad aan die ander kant met intakte filmbedekking.

LIPOGEN 40:
Wit tot naaswit, filmbedekte, ovaalvormige tablette met 'A 32' ingedruk op die een kant en glad aan die ander kant met intakte filmbedekking
LIPOGEN 80:
Wit tot naaswit, filmbedekte, ovaalvormige tablette met 'A 33' ingedruk op die een kant en glad aan die ander kant met intakte filmbedekking.
LIPOGEN tablette word in kartonne verpak wat 30 tablette bevat, verpak in kouevorm stulpstroke met 10 tablette elk.
Die koue-vorm stulpstroke bestaan uit koue-vorm gelamineerde stulpverpakking saamgestel uit aluminiumfoelie (een kant helder, saggetemper, skoon; dowwe kant lakgelamineer aan georiënteerde poliamiedfilm; helder kant lakgelamineer aan PVC film) PVC en poli-amied met ’n rugkant van aluminiumfoelie bedek met hitteseëllak aan die binnekant.
Houer van die Registrasiesertifikaat
Ranbaxy Pharmaceuticals (Pty) Ltd.
Lautreweg 14, Stormill, Uitbreiding 1
Roodepoort, 1724
Suid-Afrika

Hierdie inligtingsblad is laas hersien in

Augustus 2023

Registrasienommers
LIPOGEN 10: 42/7.5/0556
LIPOGEN 20: 42/7.5/0557
LIPOGEN 40: 42/7.5/0558
LIPOGEN 80: 42/7.5/0559
Toegang tot die ooreenstemmende Professionele Inligting
Kan vanaf die SAHPRA webwerf verkry word.

Namibië: 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 LIPOGEN 80: BOT1703035