SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM
LIPIDEX™ 10 film-coated tablets
LIPIDEX™ 20 film-coated tablets

COMPOSITION
Each **LIPIDEX 10** film-coated tablet contains: 10 mg simvastatin.
Each **LIPIDEX 10** film-coated tablet contains:
0.02 mg Butylhydroxyanisole (0.014%m/m) and 2,5 mg ascorbic acid (1,75% m/m) as antioxidant.
Contains sugar (lactose): 95,2 mg

Excipients: ascorbic acid, butylhydroxyanisole , citric acid monohydrate , hypermellose (5 cps and 15 cps) ,lactose monohydrate , magnesium stearate , microcrystalline cellulose , pregelatanised starch, talc,titatium dioxide(E171) ,red ferric oxide (E171), yellow ferric oxide (E172).

Each **LIPIDEX 20** film-coated tablet contains 20 mg simvastatin.
Each **LIPIDEX 20** film-coated tablet contains:
0.04 mg Butylhydroxyanisole (0.014%m/m) and 5,0 mg ascorbic acid (1,75% m/m) as antioxidant.
Contains sugar (lactose): 190 mg

Excipients: ascorbic acid, butylhydroxyanisole , citric acid monohydrate , hypermellose (5 cps and 15 cps) ,lactose monohydrate , magnesium stearate , microcrystalline cellulose , pregelatanised starch, talc,titatium dioxide(E171) ,red ferric oxide (E171), yellow ferric oxide (E172).

CATEGORY AND CLASS
A 7.5 Serum-cholesterol reducers

PHARMACOLOGICAL ACTION
Pharmacodynamic Properties
Simvastatin is a cholesterol-lowering agent derived synthetically from a fermentation product of *Aspergillus terreus.* After oral ingestion simvastatin, an inactive lactone, is hydrolysed to the corresponding beta-hydroxyacid, the active form. This is a principal metabolite and an inhibitor of 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase, the enzyme that catalyses the conversion of HMG-CoA to mevalonate, an early and rate-limiting step in the biosynthesis of cholesterol. As a result, simvastatin, reduces total plasma cholesterol, low-density lipoprotein (LDL) and very low-density lipoprotein (VLDL)-cholesterol concentrations. Apolipoprotein B is also decreased. In addition, simvastatin moderately increases high-density lipoprotein (HDL)-cholesterol and variably reduces plasma triglycerides.

Pharmacokinetics properties
There is extensive first-pass extraction by the liver, with oral bioavailability of the active medicine or metabolites being less than 5 %. More than 95 % of simvastatin and its beta-hydroxy metabolite are bound to plasma proteins. Following an oral dose, peak plasma concentrations of simvastatin are seen in 1 to 2 hours. Simvastatin is excreted primarily via the liver, and less than 13 % of its metabolites are excreted in the urine.

INDICATIONS
Hypercholesterolaemia:
LIPIDEX is indicated, in combination with diet, to decrease elevated serum total cholesterol and LDL-cholesterol in patients with:

- Primary hypercholesterolaemia,
- Heterozygous familial hypercholesterolaemia, or
- Mixed hyperlipidaemia, when response to diet or other nonpharmacological measures alone is not adequate.

Coronary heart disease:
LIPIDEX is indicated in patients with coronary heart disease and hypercholesterolaemia unresponsive to diet, to:

- Reduce the risk of total mortality, by reducing coronary death,
- Reduce the risk of non-fatal myocardial infarction,
- Reduce the risk of undergoing myocardial revascularisation procedures (coronary artery bypass grafting and percutaneous transluminal coronary angioplasty), and
- Slow the progression of coronary atherosclerosis

CONTRAINDICATIONS
Hypersensitivity to simvastatin, other HMG-CoA reductase inhibitors, or any of the ingredients.
Acute or chronic liver disease.
Unexplained persistent elevations of serum transaminases.
Pregnancy and lactation (see "**WARNINGS**").
Porphyria: Safety has not been established.

WARNINGS AND SPECIAL PRECAUTIONS
The active metabolite of **LIPIDEX** is fetotoxic and teratogenic in rats, and it should therefore not be used in female patients of child-bearing potential.
Use in paediatric patients is not recommended, as safety and efficacy have not been established.

Special Precautions
LIPIDEX should be used with caution in patients who:
- Consume substantial amounts of alcohol and/or who have a history of liver disease.
- May be predisposed to developing renal failure secondary to rhabdomyolysis such as in those with severe acute infection, hypotension, severe metabolic, endocrine or electrolyte disorders, uncontrolled seizures, major surgery or trauma. There is an increased risk of developing renal failure if rhabdomyolysis occurs.
- Have severe renal impairment.

Hepatic effects:
Liver function tests, including serum transaminase determinations are recommended prior to initiation of **LIPIDEX** therapy and periodically until one year after the last elevation in dose. **LIPIDEX** should be discontinued if the rise in transaminase levels is persistent and/or increases to three times or more the upper limit of normal (ULN).

Myopathy:
Reducing the risk of myopathy:
1. General measures:
   Patients starting therapy with L**IPIDEX** should be advised of the risk of myopathy and should report, promptly, unexplained muscle pain, tenderness or weakness. A creatinine kinase (CK) level above 10 times the Upper Limit of Normal (ULN) in a patient, with unexplained symptoms, indicates myopathy. **LIPIDEX** should be discontinued if myopathy is diagnosed or suspected.

2. Measures to reduce the risk of myopathy caused by medicine interactions:
   The benefits and risks of using **LIPIDEX** concomitantly with immunosuppresants, fibrates or lipid-lowering doses of niacin should be carefully considered, and the dose of **LIPIDEX** should generally not exceed 10 mg/day. Concomitant administration with cyclosporin, danazol, itraconazole, ketoconazole, erythromycin, clarithromycin, HIV-protease inhibitors and nefazodone, is not recommended.

In patients receiving cyclosporine, **LIPIDEX** should be temporarily discontinued if systemic azole derivative-antifungal therapy is required.

Contains lactose.
Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take **LIPIDEX.**

INTERACTIONS
Myopathy caused by medicine interactions:
Concomitant administration of medicines that inhibit cytochrome P450 isoenzyme CYP3A4 may result in high plasma levels of **LIPIDEX**, thus increasing the risk of myopathy, and is not recommended. Medicines that inhibit cytochrome P450 isoenzyme CYP3A4 include: cyclosporin, itraconazole, ketoconazole, erythromycin, clarithromycin, HIV-protease inhibitors and nefazodone.

The risk of myopathy is increased when other medicines that cause myopathy, such as fibrates and niacin, are given with **LIPIDEX**. A maximum dose of 10 mg **LIPIDEX** daily is recommended in patients taking cyclosporin, danazol, fibrates or lipid lowering doses of niacin (nicotinic acid).

Concurrent use of verapamil with **LIPIDEX** may be associated with an increased risk of myopathy; this effect has not been seen with other calcium channel blockers.

Grape fruit juice:
Concurrent use of **LIPIDEX** with large volumes of grape fruit juice may significantly increase the plasma concentrations of simvastatin and increase the risk of myopathy

Digoxin:
LIPIDEX may cause increases in digoxin levels.

Coumarin-derivatives (e.g. warfarin):
A possible increase in the anticoagulant effect of the coumarin anticoagulants may occur. Patients taking a coumarin anticoagulant should have their INR determined before starting **LIPIDEX** therapy. The INR should be monitored frequently enough in the early stages of therapy until stabilised. Once a stable INR has been documented, INR can be monitored at the intervals usually recommended for patients on coumarin anticoagulants. When there is a dose adjustment of **LIPIDEX**, this procedure should be repeated.

Bile acid sequestrants:
LIPIDEX should be taken 1 hour before or 4 hours after cholestyramine.
Concurrent use may decrease the bioavailability of **LIPIDEX**.

HUMAN REPRODUCTION
Safety in pregnancy and lactation has not been established.
The active metabolite of **LIPIDEX** is fetotoxic and teratogenic in rats, and it should therefore not be used in female patients of child-bearing potential.

DOSAGE AND DIRECTIONS FOR USE
The patient must follow a cholesterol-lowering diet before initiation of, and while on **LIPIDEX** therapy.

Hypercholesterolaemia:
Adults: Initial dose: 10 mg daily as a single dose in the evening.
The dose of **LIPIDEX** should be reduced if LDL-cholesterol levels fall below 1,94 mmol/l, or total plasma cholesterol levels fall below 3,6 mmol/l.

Coronary heart disease:
Adults: Initial dose: 20 mg/day as a single dose in the evening.
Dosage adjustments:
If required, the dose should be adjusted at intervals of not less than 4 weeks, up to a maximum of 80 mg daily as a single dose in the evening.
LIPIDEX can be taken with meals or on an empty stomach.

Dosage in renal insufficiency:
LIPIDEX does not undergo significant renal excretion, therefore modification of dose should not be necessary in patients with mild to moderate renal insufficiency. In patients with severe renal insufficiency **LIPIDEX** therapy should be closely monitored and doses above 10 mg/day should be implemented with caution.

Concomitant therapy:
LIPIDEX effective alone or in combination with bile acid sequestrants.
When both medicines are prescribed, **LIPIDEX** should be given 1 hour before or 4 hours after cholestyramine administration (see "Interactions"). A maximum daily dose of 10 mg **LIPIDEX** is recommended in patients taking cyclosporin, danazol, fibrates or niacin concomitantly (see "Interactions").

SIDE EFFECTS
Gastrointestinal:
Frequent: Constipation, diarrhoea, nausea, flatulence, abdominal pain.
The following have been reported and the frequencies are unknown:
Vomiting, dyspepsia and pancreatitis.

Haematological:
The following have been reported and the frequencies are unknown:
Anaemia, neutropenia.

Skin and appendages:
Frequent: Skin rash.
The following has been reported and the frequency is unknown:
Alopecia.

Musculoskeletal:
Less frequent: Myalgia, myositis, rhabdomyolysis presenting as muscle pain with elevated creatine phosphoskinase and myoglobinuria leading to renal failure.
The following have been reported and the frequencies are unknown:
Myopathy, muscle cramps.

Neurological:
Frequent: Headache, dizziness.
The following have been reported and the frequencies are unknown:
Fatigue, asthenia, paraesthesia, peripheral neuropathy.

Immune system disorders:
The following have been reported and the frequencies are unknown:
Hypersensitivity reactions that include angioedema, lupus-like syndrome, polymyalgia rheumatica, vasculitis, thrombocytopenia, increased erythrocyte sedimentation rate, eosinophilia, arthritis, arthralgia, urticaria, photosensitivity, fever, flushing, malaise and dyspnoea.

General disorders:
The following has been reported and the frequency is unknown:
Mass gain.

Laboratory test findings:
Marked and persistent increases of serum transaminases and elevated alkaline phosphatase and gamma-glutamyl transpeptidase have been reported. Liver function test abnormalities have generally been mild and transient. Increases in serum creatinine kinase (CK) levels, derived from skeletal muscle, have been reported (see "Special precautions").

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
(See "**SIDE-EFFECTS** and **WARNINGS AND SPECIAL PRECAUTIONS**").
General measures should be adopted and liver function should be monitored.
Treatment is symptomatic and supportive.

IDENTIFICATION
LIPIDEX™ 10: A peach-coloured, coated, oval, scored, convex tablet. Code SIM 10 on one side. Size: Approximately 9.8mm x 5mm
LIPIDEX™ 20: An orange-coloured coated, oval, scored, convex tablet. Code SIM 20 on one side. Size: Approximately 11.7mm x 6mm.

PRESENTATION
White opaque polyethylene (HDPE) containers and closures (tamper evident) containing 28 or 30 tablets or white opaque PVC/aluminium blister packs containing 28 or 30 tablets per carton.

STORAGE INSTRUCTIONS
Polyethylene (HDPE) containers and closures:
Keep container tightly closed. Store in a dry place, at or below 25°C. Protect from light.

White opaque PVC/aluminium blister packs:
Store in a dry place, at or below 25°C. Protect from light.
Do not remove the blisters from the outer carton until required for use.

KEEP OUT OF THE REACH OF CHILDREN

REGISTRATION NUMBER
LIPIDEX 10: 36/7.5/0213
LIPIDEX 20: 36/7.5/0214

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Oethmaan Biosims (Pty) Ltd.

14 Komatie Road
Emmarentia
Johannesburg
2195

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION
Date of registration: 29 July 2005
Date of last approval by Council: 29 July 2005
Date of revision of this package insert (Notification) : 29 June 2018

L/PI/A

SKEDULERINGSTATUS:

S4

HANDELSNAAM EN DOSEERVORM
LIPIDEX ™ 10 filmbedekte tablette
LIPIDEX ™ 20 filmbedekte tablette

SAMESTELLING
Elke **LIPIDEX 10** filmbedekte tablet bevat: 10 mg simvastatien.
Elke **LIPIDEX 10** filmbedekte tablet bevat:
0,02 mg butielhidroksianisool (0,014 % m/m) en 2,5 mg askorbiensuur (1,75 % m/m) as antioksidant.
Bevat suiker (laktose): 95,2 mg

Hulpstowwe: askorbiensuur, butielhidroksianisool, sitroensuurmonohidraat, hipromellose (5 cps en 15 cps), laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, voorafgeswelde stysel, talk, titaandioksied (E171), rooi ferrioksied (E171), geel ferrioksied (E172).

Elke **LIPIDEX** 20 filmbedekte tablet bevat 20 mg simvastatien.

Elke **LIPIDEX** 20 filmbedekte tablet bevat:
0,04 mg butielhidroksianisool (0,014 % m/m) en 5,0 mg askorbiensuur (1,75 % m/m) as antioksidant.
Bevat suiker (laktose): 190 mg

Hulpstowwe: askorbiensuur, butielhidroksianisool, sitroensuurmonohidraat, hipromellose (5 cps en 15 cps), laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, voorafgeswelde stysel, talk, titaandioksied (E171), rooi ferrioksied (E171), geel ferrioksied (E172).

KATEGORIE EN KLAS
A7.5 Middels wat cholesterol in die serum verminder

FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe
Simvastatien is 'n middel wat cholesterol verlaag en sinteties verkry word van 'n fermentasieproduk van *Aspergillus terreus*. Na orale inname word simvastatien, 'n onaktiewe laktoon, na die ooreenstemmende beta-hidroksiuur, die aktiewe vorm, gemetaboliseer. Dit is 'n hoofmetaboliet en 'n remmer van 3-hidroksi-3-metielglutariel-koënsiem A (HMG-KoA)-reduktase, die ensiem wat die omskakeling van HMG-KoA na mevalonaat kataliseer, 'n vroeë en snelheidsbeperkende stap in die biosintese van cholesterol. As gevolg hiervan verminder simvastatien die totale vlakke van cholesterol en die konsentrasies van laedigtheid lipoproteïen (LDL)-cholesterol en baie laedigtheid lipoproteïen (BLDL)-cholesterol in die plasma. Die hoeveelheid apolipoproteïen B word ook verminder. Daarby verhoog simvastatien die vlakke van hoëdigtheid lipoproteïen (HDL)-cholesterol effens en verminder op wisselende manier die hoeveelhede van trigliseriede in die plasma.

Farmakokinetiese eienskappe
Daar is grootskaalse eerstedeurgangmetabolisme in die lewer en orale biobeskikbaarheid van die aktiewe middel of metaboliete is minder as 5%. Meer as 95% van die simvastatien en sy beta-hidroksimetaboliet is aan plasmaproteïene gebind. Na 'n orale dosis word piek plasmakonsentrasies van simvastatien na 1 tot 2 uur waargeneem. Simvastatien word hoofsaaklik deur die lewer uitgeskei en minder as 13 % van sy metaboliete word in die urien uitgeskei.

INDIKASIES
Hipercholesterolemie

LIPIDEX is, in kombinasie met dieet, aangedui om die totale hoeveelheid cholesterol en LDL-cholesterol te verlaag in die serum van pasiënte met
- primêre hipercholesterolemie,
- heterosigote familiële hipercholesterolemie of
- gemengde hiperlipidemie, as respons op dieet of ander nie-farmakologiese maatreëls nie voldoende is nie.

Koronêre hartsiekte

LIPIDEX is aangedui vir pasiënte met koronêre hartsiekte en hipercholesterolemie wat nie op dieet reageer nie ten einde
- die risiko vir totale mortaliteit deur koronêre sterftes te verminder,
- die risiko vir nie-fatale miokardiale infarksie te verminder,
- die risiko vir miokardiale revaskularisasieprosedures te verminder (hartomleidingsoperasie en perkutane transluminêre koronêre angioplastie), en
- die vordering van koronêre aterosklerose te vertraag

KONTRA-INDIKASIES
Hipersensitiwiteit teenoor simvastatien, ander HMG-KoA-reduktaseremmers, of enige van die bestanddele.

Akute of chroniese lewersiekte.

Onverklaarde hardnekkige toename in serumtransaminases.

Swangerskap en borsvoeding (kyk "**WAARSKUWINGS**").

Porfirie: Die veiligheid is nie bepaal nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS
Die aktiewe metaboliet van **LIPIDEX** is fetotoksies en teratogenies in rotte en dit moet dus nie gebruik word vir vroulike pasiënte wat swanger kan raak nie.

Die gebruik in pediatriese pasiënte word nie aanbeveel nie omdat die veiligheid en effektiwiteit nie bepaal is nie.

Spesiale voorsorgmaatreëls

LIPIDEX moet versigtig gebruik word deur pasiënte wat:
- Substansiële hoeveelhede alkohol gebruik en/of wat 'n geskiedenis van lewersiekte het.
- Geneig kan wees om vanweë rabdomiolise nierversaking te ontwikkel soos diegene met erge akute infeksie, hipotensie, erge metaboliese, endokrien- of elektrolietversteurings, onbeheerde toevalle, groot operasie of trauma. Daar is 'n groter risiko dat nierversaking kan ontwikkel as rabdomiolise voorkom.
- Erge swak nierfunksie.

Effekte op die lewer
Lewerfunksietoetse, waaronder bepalings van transaminases in die serum, word aanbeveel voor aanvang van behandeling met **LIPIDEX** en periodiek tot een jaar na die laaste verhoging in die dosis. **LIPIDEX** moet gestaak word as die toename in vlakke van transaminases voortduur en/of tot drie keer of meer die boonste limiet (BLN) van normaal bereik.

Miopatie
Om die risiko's vir miopatie te verlaag

1. Algemene maatreëls:

   Pasiënte wat met behandeling met **LIPIDEX** begin, moet ingelig word oor die risiko vir miopatie en moet onverklaarde spierpyn, teerheid of swakheid onmiddellik aanmeld. 'n Vlak van kreatinienkinase hoër as 10 keer die boonste limiet van normaal (BLN) met onverklaarde simptome is aanduidend van miopatie. **LIPIDEX** moet gestaak word as miopatie gediagnoseer of vermoed word.

2. Maatreëls om die risiko vir miopatie veroorsaak deur medisyne-interaksies te verminder

   Die voordele en risiko's van die gebruik van **LIPIDEX** saam met imuunonderdrukkers, fibrate of dosisse van niasien wat lipiede verlaag, moet noukeurig oorweeg word en die dosis van **LIPIDEX** moet gewoonlik nie 10 mg per dag oorskry nie. Gelyktydige toediening van siklosporien, danasol, itrakonasool, ketokonasool, eritromisien, klaritromisien, MIV-proteaseremmers en nefasodoon word nie aanbeveel nie.

Behandeling met **LIPIDEX** moet tydelik gestaak word in pasiënte wat siklosporien ontvang as behandeling met 'n asoolderivaat vir fungusinfeksie nodig is.

Bevat laktose.
Pasiënte met die skaars oorerflike toestand van onverdraagbaarheid van galaktose, die Laplandse laktasetekort of wanabsorpsie van glukose/galaktose of met onverdraagbaarheid van fruktose, moet nie **LIPIDEX** drink nie.

INTERAKSIES

Miopatie veroorsaak deur medisyne-interaksies

Medisyne wat sitochroom P450 iso-ensiem CYP3A4 rem, kan tot hoë vlakke van **LIPIDEX** in die plasma lei en die risiko vir miopatie dus verhoog en word nie aanbeveel nie. Medisyne wat sitochroom P450 iso-ensiem CYP3A4 rem, is onder meer siklosporien, itrakonasool, ketokonasool, eritromisien, klaritromisien, MIV-proteaseremmers en nefasodoon.

Die risiko vir miopatie is hoër as ander medisyne wat miopatie veroorsaak, soos fibrate en niasien, saam met **LIPIDEX** gegee word. 'n Maksimum dosis van 10 mg **LIPIDEX** daagliks word aanbeveel vir pasiënte wat siklosporien, danasol, fibrate of dosisse van niasien (nikotiensuur) wat lipiede verlaag gebruik.

Gebruik van verapamiel saam met **LIPIDEX** kan met 'n groter risiko vir miopatie gepaardgaan; hierdie effek is nie met ander kalsiumkanaalblokkers gesien nie.

Pomelosap
Gebruik van **LIPIDEX** saam met groot volumes pomelosap kan die plasmakonsentrasies van simvastatien aansienlik verhoog en die risiko vir miopatie verhoog.

Digoksien
LIPIDEX kan toenames in die vlakke van digoksien veroorsaak.
'n Moontlike versterking van die antikoagulanteffek van die kumarienantikoagulante kan voorkom. Pasiënte wat kumarienantikoagulante gebruik, moet hulle INR laat bepaal voordat hulle met behandeling met **LIPIDEX** begin. Die INR moet gereeld genoeg in die vroeë stadium van behandeling gemonitor word totdat dit stabiel is. Sodra 'n stabiele INR bereik is, kan die INR gemonitor word met die intervalle wat gewoonlik aanbeveel word vir pasiënte wat kumarien gebruik. As daar 'n aanpassing in die dosis van **LIPIDEX** is, moet die prosedure herhaal word.

Galsuurbinders
LIPIDEX moet 1 uur voor of 2 uur na cholestiramien gedrink word.
Gelyktydige gebruik kan die biobeskikbaarheid van **LIPIDEX** verlaag.

MENSLIKE VOORTPLANTING
Die veiligheid tydens swangerskap en borsvoeding is nie bepaal nie.
Die aktiewe metaboliet van **LIPIDEX** is fetotoksies en teratogenies in rotte en dit moet dus nie gebruik word vir vroulike pasiënte wat swanger kan raak nie.

DOSIS EN GEBRUIKSAANWYSINGS
Die pasiënt moet voor aanvang van of tydens behandeling met **LIPIDEX** 'n dieet volg wat cholesterolvlakke verlaag.

Hipercholesterolemie
Volwassenes: Aanvangsdosis: 10 mg daagliks as 'n enkele dosis in die aand.

Die dosis van **LIPIDEX** moet verlaag word as die vlakke van LDL-cholesterol tot onder 1,94 mmol/l val of as die totale cholesterolvlakke in die plasma tot onder 3,6 mmol/l val.

Koronêre hartsiekte
Volwassenes: Aanvangsdosis: 20 mg per dag as 'n enkele dosis in die aand.

Aanpassing in die dosis
Indien nodig, kan die dosis met intervalle van nie minder nie as 4 weke aangepas word tot 'n maksimum van 80 mg per dag as 'n enkele dosis in die aand.

LIPIDEX kan tydens etes of op 'n leë maag gedrink word.

Dosis vir pasiënte met swak nierfunksie
LIPIDEX ondergaan nie beduidende uitskeiding deur die niere nie en daarom is 'n aanpassing in die dosis nie nodig vir pasiënte met ligte tot matige swak nierfunksie nie. Vir pasiënte met erge swak nierfunksie moet behandeling met **LIPIDEX** noukeurig gemonitor word en dosisse groter as 10 mg per dag moet versigtig gebruik word.

Gelyktydige behandeling
LIPIDEX is effektief alleen of in kombinasie met galsuurbinders.
As albei middels voorgeskryf word, moet **LIPIDEX** 1 uur voor of 4 uur na toediening van cholestiramien gegee word (kyk "Interaksies"). 'n Maksimum daaglikse dosis van 10 mg **LIPIDEX** word aanbeveel vir pasiënte wat siklosporien, fibrate of niasien terselfdertyd gebruik (kyk 'Interaksies').

NEWE-EFFEKTE

Gastro-intestinaal
Dikwels: Hardlywigheid, diarree, naarheid, winderigheid, buikpyn
Die volgende het voorgekom en die frekwensies is onbekend:
Braking, dispepsie en pankreatitis

Hematologies
Die volgende het voorgekom en die frekwensies is onbekend:
Anemie, neutropenie

Vel en aanhangsels
Dikwels: Veluitslag
Die volgende het voorgekom en die frekwensies is onbekend:
Alopesie

Muskuloskeletaal
Minder dikwels: Mialgie, miositis, rabdomiolise wat as spierpyn voorkom met hoër vlakke kreatinienfosfokinase en mioglobinurie wat tot nierversaking lei
Die volgende het voorgekom en die frekwensies is onbekend:
Miopatie, spierkrampe

Neurologies
Dikwels: Hoofpyn, duiseligheid
Die volgende het voorgekom en die frekwensies is onbekend:
Moegheid, astenie, parestesie, perifere neuropatie

Versteurings van die immuunstelsel
Die volgende het voorgekom en die frekwensies is onbekend:
Hipersensitiwiteitsreaksies wat angio-edeem, 'n lupus-agtige sindroom, polymyalgia rheumatica, vaskulitis, trombositopenie, 'n hoër besinkingstempo, eosinofilie, artritis, artralgie, urtikarie, fotosensitiwiteit, koors, blosing, ongesteldheid en dispnee insluit.

Algemene versteurings
Die volgende het voorgekom en die frekwensies is onbekend:
Toename in massa

Uitslae van laboratoriumtoetse

Merkbare en volgehoue toenames van transaminases in die serum en hoër vlakke van alkaliese fosfatase en gammaglutamieltranspeptidase is aangemeld. Abnormaliteite in lewerfunksie was gewoonlik lig en verbygaande. Toenames in die serumvlakke van kreatinienkinase (KK) afkomstig van skeletspiere is aangemeld (kyk "Spesiale voorsorgmaatreëls").

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
(Kyk "**NEWE EFFEKTE**" en "**WAARSKUWINGS en SPESIALE VOORSORGMAATREëLS**").
Algemene maatreëls moet getref word en lewerfunksie moet gemonitor word.
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

LIPIDEX 10 'n Perskekleurige, bedekte, ovaal, konvekse tablet met 'n breeklyn. Kode SIM op een kant gedruk.
Grootte: Ongeveer 9.8 mm x 5 mm

LIPIDEX 20 'n Oranjekleurige, bedekte, ovaal, konvekse tablet met 'n breeklyn. Kode SIM 20 op een kant gedruk.
Grootte: Ongeveer 11,7 mm x 6 mm

AANBIEDING
Houers en proppe (peuterbestand) van wit, ondeursigtige hoëdigtheidpoliëtileen (HDPE) met 28 of 30 tablette of stulppakke van wit ondeursigtige PVC/aluminium met 28 of 30 tablette per karton bevat.

BEWARINGSINSTRUKSIES
Houers en proppe van poliëtileen (HDPE)
Hou die houer dig toe. Bêre op 'n droë plek by of onder 25 °C. Beskerm teen lig.

Wit, ondeursigtige PVC/aluminium-stulpstroke
Bêre op 'n droë plek by of onder 25 °C. Beskerm teen lig.
Moenie die stulppakke uit die karton verwyder voordat dit benodig word nie.

HOU BUITE BEREIK VAN KINDERS

REGISTRASIENOMMER

LIPIDEX 10 36/7,5/0213

LIPIDEX 20 36/7,5/0214

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

Oethmaan Biosims (Pty) Ltd.

Komatieweg 14
Emmarentia
Johannesburg
2195.

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