Front Side

300 mm

SITACLEOD
25/50/100
PM04336957

SCHEDULING STATUS: S3

SITACLEOD 25 mg (film-coated tablets)
Contains 31,015 mg of Sitagliptin Phosphate (Monohydrate), which is equivalent to 25 mg of free base.
Sugar free

SITACLEOD 50 mg (film-coated tablets)
Contains 62,030 mg of Sitagliptin Phosphate (Monohydrate), which is equivalent to 50 mg of free base.
Sugar free

SITACLEOD 100 mg (film-coated tablets)
Contains 124,060 mg of Sitagliptin Phosphate (Monohydrate), which is equivalent to 100 mg of free base.
Sugar free

Read all of this leaflet carefully before you start taking SITACLEOD
Keep this leaflet. You may need to read it again.
If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
SITACLEOD 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 **SITACLEOD** is and what it is used for
2. What you need to know before you take **SITACLEOD**
3. How to take **SITACLEOD**
4. Possible side effects
5. How to store **SITACLEOD**
6. Contents of the pack and other information

1. What SITACLEOD is and what it is used for

SITACLEOD (sitagliptin phosphate) is a tablet that contains 25, 50 or 100 mg of sitagliptin as the active ingredient.
SITACLEOD belongs to a class of medicines you take by mouth, called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in patients with type 2 diabetes mellitus. Type 2 diabetes is also called non-insulin-dependent diabetes mellitus or NIDDM.
SITACLEOD helps to improve the levels of insulin after a meal.
Your doctor has prescribed **SITACLEOD** to help lower your blood sugar levels, which is too high because you have type 2 diabetes. **SITACLEOD** can be used alone or in combination with certain other medicines that lower blood sugar levels, along with a recommended diet and exercise program.

2. What you need to know before you take SITACLEOD

Do not take SITACLEOD:
- If you are allergic to sitagliptin or any of the other ingredients listed in section 6.
- If you suffer from liver disease

Warnings and precautions
Take special care with **SITACLEOD**
Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving **SITACLEOD** (see section 4).
If you encounter blistering of the skin it may be a sign for a condition called bullous pemphigoid. Your doctor may ask you to stop **SITACLEOD**.

Hypersensitivity reactions
Post-marketing reports of serious hypersensitivity reactions in patients treated with sitagliptin have been reported. These reactions include anaphylaxis, angioedema, and exfoliative skin conditions including Stevens - Johnson syndrome. Onset of these reactions occurred within the first 3 months after initiation of treatment, with some reports occurring after the first dose. If a hypersensitivity reaction is suspected, SITACLEOD should be discontinued. Other potential causes for the event should be assessed, and alternative treatment for diabetes initiated.

Tell your doctor if you have or have had:
- a disease of the pancreas (such as pancreatitis)
- type 1 diabetes
- diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting)
- any past or present kidney problems

SITACLEOD is unlikely to cause low blood sugar because it does not work when your blood sugar is low. However, when this medicine is used in combination with a sulphonylurea medicine or with insulin, low blood sugar (hypoglycaemia) can occur. Your doctor may reduce the dose of your sulphonylurea or insulin medication.

Children and adolescents
Children and adolescents below 18 years should not use this medicine. It is not effective in children and adolescents between the ages of 10 and 17 years. It is not known if this medicine is safe and effective when used in children younger than 10 years.

Other medicines and SITACLEOD
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Tell your doctor or pharmacist if you are taking any of the following medicines:
In particular, tell your doctor if you are taking digoxin (a medicine used to treat irregular heart beat and other heart problems). The level of digoxin in your blood may need to be checked if taking with **SITACLEOD**.

Pregnancy, breastfeeding 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.
You should not take this medicine during pregnancy.
It is not known if this medicine passes into breast milk. You should not take this medicine if you are breast-feeding or plan to breast-feed.

Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines. However, dizziness and drowsiness have been reported, which may affect your ability to drive or use machines.
Taking this medicine in combination with medicines called sulphonylureas or with insulin can cause hypoglycaemia, which may affect your ability to drive and use machines or work without safe foothold.

SITACLEOD contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'

3. How to take SITACLEOD

Do not share medicines prescribed for you with any other person.
Always take **SITACLEOD** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
The recommended dose to take is:
One 100 mg tablet once a day by mouth, with or without food.
If you have the impression that the effect of **SITACLEOD** is too strong or too weak, talk to your doctor or pharmacist.
If you have kidney problems, your doctor may prescribe lower doses (such as 25 mg or 50 mg).
Your doctor may prescribe **SITACLEOD** along with certain other medicines that lower blood sugar levels. Remember to take all medicines as directed by your doctor to achieve the best results for your health.
Diet and exercise can help your body use its blood sugar better. It is important to stay on your doctor recommended diet, exercise and weight loss program while taking **SITACLEOD**. Check your blood sugar as your healthcare professional tells you to.

Method of administration
Swallow the tablet whole with water. You can take the tablet with or without food. You can take the tablet at any time of the day. However, try to take it at the same time each day. This will help you to remember to take it.

If you take more SITACLEOD than you should
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take SITACLEOD
It is important to take your **SITACLEOD** regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose do not take a double dose to make up for a forgotten dose. Never take two doses on the same day.

If you stop taking SITACLEOD
If **SITACLEOD** is stopped earlier than your doctor has prescribed, your blood sugar levels may increase. Always take **SITACLEOD** for as long as your doctor has prescribed.

4. Possible side effects

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

If any of the following happens, stop taking **SITACLEOD** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Allergic reactions which may be serious including rash, hives and swelling of the face, lips, tongue and throat that may cause difficulty in breathing or swallowing. If you have an allergic reaction, stop taking **SITACLEOD** and call your doctor right away. Your doctor may prescribe a medication to treat your allergic reaction and a different medication for your diabetes.
- Severe and persistent stomach pain, often with nausea and vomiting. These may be symptoms of pancreatitis. Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking **SITACLEOD** and call your doctor right away if you experience these symptoms. This may occur regardless of your blood glucose (sugar) level. Your doctor may decide to temporarily or permanently stop your treatment with **SITACLEOD**. Please see also the section "**Take special care with SITACLEOD**."

These are all very serious side effects. If you have them, you may have had a serious reaction to **SITACLEOD**. 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:
- Low blood sugar (hypoglycaemia), seen frequently when taking **SITACLEOD** with sulphonylurea or with insulin.

The signs of low blood sugar may include:
- Jitteriness, sweating, feeling very anxious or confused, fast heart beat
- Excessive hunger, headache.

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

Tell your doctor if you notice any of the following:

Frequent
- Headache
- Nausea (feeling sick)
- Flatulence (gas)
- swelling

Less frequent
- Dizziness
- Constipation
- Itchy skin
- Thrombocytopenia – a reduced number of platelets
- Sleepiness
- Diarrhoea
- Upper abdominal pain

Frequency unknown
- Interstitial lung disease – a large group of diseases that cause scarring of the lungs
- Vomiting
- Swelling of the skin, rash, hives, painful blisters on the skin or peeling skin
- Muscle aches, backache, joint diseases
- Kidney problems
- If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Should your general health worsen or if you experience any untoward effects while taking **SITACLEOD**, please consult your healthcare provider for advice.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA and eReporting platform (whi-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **SITACLEOD.**

5. How to store SITACLEOD

Store at or below 30 °C.
KEEP OUT OF THE REACH OF CHILDREN.
Store in the original package / container.
Keep the blisters in the carton until required for use.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister /label/carton bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What SITACLEOD contains
The active ingredient is Sitagliptin.
The other ingredients are:
Microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, povidone, sodium stearyl fumarate, magnesium stearate.
Film coating contains: hypromellose 6 cPs, polyethylene glycol 400, polyethylene glycol 6000, talc, titanium dioxide (C.I. No. 77891), red iron oxide (C.I. No. 77491), yellow iron oxide (C.I. No. 77492)

What SITACLEOD looks like and contents of the pack
SITACLEOD 25 mg: Each film-coated tablet contains 31,015 mg of Sitagliptin Phosphate (Monohydrate), which is equivalent to 25 mg of free base.
SITACLEOD 50 mg: Each film-coated tablet contains 62,030 mg of Sitagliptin Phosphate (Monohydrate), which is equivalent to 50 mg of free base.
SITACLEOD 100 mg: Each film-coated tablet contains 124,060 mg of Sitagliptin Phosphate (Monohydrate), which is equivalent to 100 mg of free base.

Contents of the pack:
Blister pack:
Tablets are packed in cold form laminate 25 µm OPA/45 µm aluminum foil/60 µm PVC as the forming material and 25 µ aluminium plain foil/ 6-8 gsm heat seal lacquer as the lidding material, packed in a pre-printed carton.
Pack size includes 10's, 28's and 30's tablets.
HDPE container:
Tablets are packed in 60 ml round, white, HDPE container, 33 mm neck finish with 33 mm polypropylene white closure with Pulp and white printed Heat Seal Liner with or without silica gel.
Pack size: 30's
Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD
Ground Floor, Block 1,
Bassonia Estate Office Park (East),
1 Cussonia Drive,
Bassonia Rock Ext 12
Alberton
Gauteng

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Registration numbers
SITACLEOD 25 mg: 56/21.2/1159
SITACLEOD 50 mg: 56/21.2/1160
SITACLEOD 100 mg: 56/21.2/1161

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodssaproducts.co.za or email macleodsrsa@macleodspharma.com or contact 011 682 1169

335 mm

Back Side

PASIËNTINLIGTINGSTUK S3

SITACLEOD 25 mg (filmbedekte tablette)
Bevat 31,015 mg van Sitagliptienfosfaat (Monohidraat), wat gelykstaande is aan 25 mg van vrye basis.
Suikervry

SITACLEOD 50 mg (filmbedekte tablette)
Bevat 62,030 mg van Sitagliptienfosfaat (Monohidraat), wat gelykstaande is aan 50 mg van vrye basis.
Suikervry

SITACLEOD 100 mg (filmbedekte tablette)
Bevat 124,060 mg van Sitagliptienfosfaat (Monohidraat), wat gelykstaande is aan 100 mg van vrye basis.
Suikervry

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy SITACLEOD begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **SITACLEOD** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

1. Wat **SITACLEOD** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **SITACLEOD** neem
3. Hoe om **SITACLEOD** te neem
4. Moontlike newe-effekte
5. Hoe om **SITACLEOD** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat SITACLEOD is en waarvoor dit gebruik word

SITACLEOD (sitagliptienfosfaat) is 'n tablet wat 25, 50 of 100 mg sitagliptien as die aktiewe bestanddeel bevat.
SITACLEOD behoort tot 'n klas van medisyne wat jy per mond neem, genaamd DPP-4-remmers (dipeptidiel-peptidase-4-remmers) wat bloedsuikervlakke verlaag in pasiënte met tipe 2-diabetes mellitus. Tipe 2-diabetes word ook nie-insulien afhanklike diabetes mellitus of NIDDM genoem.
SITACLEOD help om die vlakke van insulien na 'n maaltyd te verbeter.
Jou dokter het **SITACLEOD** voorgeskryf om jou bloedsuikervlakke, wat te hoog is omdat jy tipe 2-diabetes het, te help verlaag. **SITACLEOD** kan alleen of in kombinasie met sekere ander medisyne gebruik word wat bloedsuikervlakke verlaag, tesame met 'n aanbevole dieet- en oefenprogram.

2. Wat jy behoort te weet voordat jy SITACLEOD neem

Moet nie SITACLEOD neem nie:
- Indien jy allergies is vir sitagliptien of enige van die ander bestanddele gelys in afdeling 6.
- Indien jy ly aan lewersiekte

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **SITACLEOD**
Gevalle van ontsteking van die pankreas (pankreatitis) is al aangemeld in pasiënte wat **SITACLEOD** ontvang het (sien afdeling 4).
Indien jy blase van die vel teëkom, kan dit 'n teken wees van 'n toestand naamlik blasige blaarkoorsvorming.
Jou dokter kan jou vra om **SITACLEOD** te staak.

Hipersensitiwiteits reaksies
Na-bemarkingsverslae van ernstige hipersensitiwiteits reaksies in pasiënte wat met sitagliptien behandel is, is aangemeld. Hierdie reaksies sluit in anafilakse, angioëdeem en afskilferende veltoestande, insluitend Stevens-Johnson - sindroom. Die aanvang van hierdie reaksies het binne die eerste 3 maande na die aanvang van die behandeling plaasgevind, met sommige verslae wat na die eerste dosis plaasgevind het. Indien 'n hipersensitiwiteits reaksie vermoed word, moet **SITACLEOD** gestaak word. Ander moontlike oorsake vir die gebeurtenis moet vasgestel word, en alternatiewe behandeling vir diabetes moet begin word.

Vertel jou dokter indien jy het of gehad het:
- 'n siekte van die pankreas (soos pankreatitis)
- tipe 1 diabetes
- diabetiese keto-asidose ('n komplikasie van diabetes met hoë bloedsuiker, vinnige gewigsverlies, naarheid of braking)
- enige vorige of huidige nierprobleme

SITACLEOD is onwaarskynlik om lae bloedsuiker te veroorsaak, aangesien dit nie werk wanneer jou bloedsuiker laag is nie. Wanneer hierdie medisyne egter in kombinasie met 'n sulfonielureum medisyne of met insulien gebruik word, kan lae bloedsuiker (hipoglukemie) voorkom. Jou dokter kan die dosis van jou sulfonielureum- of insulienmedikasie verminder.

Kinders en adolessente
Kinders en adolessente jonger as 18 jarige ouderdom moet nie hierdie medisyne gebruik nie. Dit is nie effektief in kinders en adolessente tussen die ouderdomme van 10 en 17 jarige ouderdom nie. Dit is nie bekend of hierdie medisyne veilig en doeltreffend is wanneer dit in kinders jonger as 10 jaar oud gebruik word nie.

Ander medisyne en SITACLEOD
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel vir jou dokter of apteker as jy enige van die volgende medisyne neem.
Vertel veral jou dokter indien jy digoksien neem ('n medisyne wat gebruik word om onreëlmatige hartklop en ander hartprobleme te behandel). Die vlak van digoksien in jou bloed moet moontlik nagegaan word indien dit saam met **SITACLEOD** geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, vermoed dat jy moontlik swanger is, of beplan om 'n baba te hê, vra asseblief jou dokter of apteker vir advies voordat jy hierdie medisyne neem.
Jy moet nie hiedie medisyne neem gedurende swangerskap nie.
Dit is nie bekend of hierdie medisyne in borsmelk oorgaan nie. Jy moet nie hierdie medisyne neem indien jy borsvoed of beplan om te borsvoed nie.

Bestuur en gebruik van masjinerie
Hierdie medisyne het geen of weglaatbare invloed op die vermoë om te bestuur en masjiene te gebruik. Duiseligheid en slaperigheid is egter al aangemeld, wat jou vermoë om te bestuur of om masjiene te gebruik, kan affekteer.
Neem van hierdie medisyne in kombinasie met medisyne naamlik sulfonielureum of met insulien kan hipoglukemie veroorsaak, wat jou vermoë om te bestuur en masjiene te gebruik of werk sonder veilige vastrapplek, kan beïnvloed.

SITACLEOD bevat minder as 1 mmol natrium (23 mg) per tablet, dit is so te sê in wese 'natriumvry'.

3. Hoe om SITACLEOD te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem altyd **SITACLEOD** presies soos wat jou dokter jou opdrag gegee het. Jy moet met jou dokter of apteker bevestig indien jy nie seker is nie.
Die aanbevole dosis om te neem is:
Een 100 mg tablet een keer per dag per mond, met of sonder kos.
Indien jy die indruk kry dat die effek van **SITACLEOD** te sterk of te swak is, praat met jou dokter of apteker.
Indien jy nierprobleme het, kan jou dokter laer dosisse voorskryf (soos 25 mg of 50 mg).
Jou dokter kan **SITACLEOD** saam met sekere ander medisyne voorskryf wat bloedsuikervlakke verlaag. Onthou om alle medisyne te neem soos deur jou dokter voorgeskryf om die beste resultate vir jou gesondheid te behaal.
Dieet en oefening kan jou liggaam help om sy bloedsuiker beter te gebruik. Dit is belangrik om op jou dokter se aanbevole dieet, oefening en gewigsverliesprogram te bly terwyl jy **SITACLEOD** neem. Kontroleer jou bloedsuiker soos wat jou professionele gesondheidsorgwerker jou aansê om te doen.

Metode van toediening
Sluk die tablet heel met water. Jy kan die tablet met of sonder kos neem. Jy kan die tablet op enige tyd van die dag neem. Probeer egter om dit elke dag op dieselfde tyd te neem. Dit sal jou help om te onthou om dit te neem.

Indien jy meer SITACLEOD neem as wat jy moet
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om SITACLEOD te neem
Dit is belangrik om jou **SITACLEOD** gereeld op dieselfde tyd elke dag te neem. Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy daarvan onthou, tensy dit tyd is vir jou volgende dosis. Moet nie 'n dubbele dosis neem, om op te maak vir 'n vergete dosis nie. Moet nooit twee dosisse op dieslefde dag neem nie.

Indien jy ophou om SITACLEOD te neem
Indien **SITACLEOD** vroeër gestaak word as wat jou dokter voorgeskryf het, kan jou bloedsuikervlakke toeneem. Neem altyd **SITACLEOD** vir so lank as wat jou dokter voorgeskryf het.

4. Moontlike newe-effekte

SITACLEOD kan newe-effekte hê.
Nie alle newe-effekte wat vir **SITACLEOD** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verswak of indien jy enige ongunstige effekte ervaar terwyl jy **SITACLEOD** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om **SITACLEOD** te neem en vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- Allergiese reaksies wat ernstig kan wees, insluitend uitslag, galbulte en swelling van die gesig, lippe, tong en keel wat probleme met asemhaling of sluk kan veroorsaak. Indien jy 'n allergiese reaksie het, hou op om **SITACLEOD** te neem en bel onmiddellik jou dokter. Jou dokter kan 'n middel voorskryf om jou allergiese reaksie te behandel en 'n ander medikasie vir jou diabetes.
- Erge en aanhoudende maagpyn, dikwels met naarheid en braking. Dit kan simptome van pankreatitis wees. Pankreatitis kan 'n ernstige, potensieel lewensgevaarlike mediese toestand wees. Hou op om **SITACLEOD** te neem en bel onmiddellik jou dokter indien jy hierdie simptome ervaar. Dit kan voorkom ongeag van jou bloedglukose (suiker) vlak. Jou dokter kan besluit om jou behandeling met **SITACLEOD** tydelik of permanent te staak. Sien asseblief ook die afdeling "**Neem spesiale sorg met SITACLEOD".**

Hierdie is amal baie ernstige newe-effekte. Indien jy dit het, het jy moontlik 'n ernstige reaksie op **SITACLEOD** gehad. Jy benodig moontlik dringende mediese aandag of hospitalisering.
Vertel onmiddellik jou dokter, of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- Lae bloedsuiker (hipoglukemie), dikwels gesien wanneer **SITACLEOD** saam met sulfonielureum of met insulien geneem word.

Die tekens van lae bloedsuiker kan insluit:
- Gejaagheid, sweet, baie angstig of verward voel, vinnige hartklop
- Oormatige honger, hoofpyn.

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

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereeld
- Hoofpyn
- Naarheid (siek wees)
- Winderigheid (gas)
- swelling

Minder gereeld
- Duiseligheid
- Hardlywigheid
- Jeukende vel
- Trombositopenie – 'n verminderde aantal bloedplaatjies
- Slaperigheid
- Diarree
- Boonste abdominale pyn

Frekwensie onbekend
- Interstisiële longsiekte – 'n groot groep siektes wat littekens van die longe veroorsaak
- Braking
- Swelling van die vel, uitslag, galbulte, pynlike blase op die vel of vel wat afskilfer
- Spierpyne, rugpyn, gewrigsiektes
- Nier probleme
- Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem is nie, stel asseblief jou dokter of apteker in kennis

Sou jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl **SITACLEOD** geneem word, konsulteer asseblief met jou gesondheidsorgverskaffer vir advies.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die Med Safety APP (Medsafety X SAHPRA en eReporting platform (whi-umc.org) gevind op SAHPRA se webwerf. Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **SITACLEOD**.

5. Hoe om SITACLEOD te bewaar

Bewaar by of benede 30 °C.
HOU BUITE DIE BEREIK VAN KINDERS.
Bewaar in die oorspronklike verpakking / houer.
Hou die stulpstroke in die karton totdat dit benodig word vir gebruik.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat op die stulpstrook / etiket / karton / bottel aangebring is nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van pak en ander inligting

Wat SITACLEOD bevat
Die aktiewe bestanddeel is Sitagliptien.
Die ander bestanddele is:
Mikrokristallyne sellulose, watervrye dibasiese kalsiumfosfaat, natriumkruiskarmellose, povidoon, natriumstearielfumaraat, magnesiumstearaat.
Filmbedekking bevat: hipromellose 6 cP's, poliëtileenglikol 400, poliëtileenglikol 6 000, talk, titaandioksied (CI-nr. 77891), rooi ysteroksied (CI-nr. 77491), geel ysteroksied (CI-nr. 77492)

Hoe SITACLEOD lyk en die inhoud van die pak
SITACLEOD 25 mg: Elke filmbedekte tablet bevat 31,015 mg van Sitagliptienfosfaat (Monohidraat), wat gelykstaande is aan 25 mg van vrye basis.
SITACLEOD 50 mg: Elke filmbedekte tablet bevat 62,030 mg van Sitagliptienfosfaat (Monohidraat), wat gelykstaande is aan 50 mg van vrye basis.
SITACLEOD 100 mg: Elke filmbedekte tablet bevat 124,060 mg van Sitagliptienfosfaat (Monohidraat), wat gelykstaande is aan 100 mg van vrye basis.

Inhoud van die pak:
Stulpstrook pak:
Tablette word verpak in koue vorm laminaat 25 µm OPA / 45 µm aluminiumfoelie / 60 µm PVC as die vormingsmateriaal en 25 µ aluminium gewone foelie / 6-8 gsm hitte seëllak as die dekmateriaal, verpak in 'n voorafgedrukte karton.
Verpakkingsgrootte sluit 10'e, 28's en 30's tablette in.
HDPE-houer:
Tablette word verpak in 60 ml ronde, wit HDPE-houer, 33 mm nekafwerking met 33 mm polipropileen wit sluiting met Pulp en wit gedrukte Heat Seal Liner met of sonder silikagel.
Verpakkingsgrootte: 30's
Nie alle verpakkingsgroottes word noodwendig bemark nie.

7. HOUER VAN SERTIFIKAAT VAN REGISTRASIE

MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Grondvloer, Blok 1,
Bassonia Estate Kantoorpark (Oos),
Cussonia-rylaan 1,
Bassonia Rock, Uitbr. 12,
Alberton
Gauteng

Hierdie inligtingstuk is laas hersien in
26 Julie 2024

Registrasienommers
SITACLEOD 25 mg: 56/21.2/1159
SITACLEOD 50 mg: 56/21.2/1160
SITACLEOD 100 mg: 56/21.2/1161

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodssaproducts.co.za of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169

300 mm

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: SITACLEODS 25/50/100 (Sitagliptin Film Coated Tablets 25/50/100 mg)	
2. Country: South Africa	**3. Packaging component: Patient Information**
4. No. of Colours: 1 Colour	**5. Pantone Shade No.: Black**
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	**8. Dimensions: 335 (L) x 300 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM04336957**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 34752 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: NA**
15. Revision No: 00	**16. A/W File name: Z:\Sitagliptin\Private market\SITACLEOD 25-50- 100mg PIL - PM04336957.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	05/03/2025				

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-01

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa	PM04336957		