# Front Side

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS** S3

**VIMCOSA 50 mg** (film coated tablet)
**VIMCOSA 100 mg** (film coated tablet)
**VIMCOSA 150 mg** (film coated tablet)
**VIMCOSA 200 mg** (film coated tablet)
Lacosamide
Sugar-Free

**Read all of this leaflet carefully before you start taking VIMCOSA**
- 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.
- **VIMCOSA** 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 **VIMCOSA** is and what it is used for
2. What you need to know before you take **VIMCOSA**
3. How to take **VIMCOSA**
4. Possible side effects
5. How to store **VIMCOSA**
6. Contents of the pack and other information


**1. What VIMCOSA is and what it is used for**

**VIMCOSA** contains lacosamide.
Lacosamide belongs to a group of medicines called "antiepileptic medicines". These medicines are used to treat epilepsy.
- You have been given this medicine to lower the number of fits (seizures) you have.

**VIMCOSA** is used for:
children aged 2 years and older to treat a certain type of epilepsy characterised by the occurrence of partial-onset seizure with or without secondary generalisation. In this type of epilepsy, fits first affect only one side of your brain. However, these may then spread to larger areas on both sides of your brain;

in association with other antiepileptic medicines in adults, adolescents and children aged 4 years and older to treat primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in patients with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

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

**Do not take VIMCOSA:**
- If you are hypersensitive (allergic) to lacosamide or any of the other ingredients of this medicine, listed in section 6.
- If you have a certain type of heart beat problem called second- or third-degree AV block.

**Warnings and precautions**
Talk to your doctor before taking **VIMCOSA**
Before you start taking **VIMCOSA**, tell your doctor if you have or have ever had:
- You have thoughts of harming or killing yourself. Some people being treated with antiepileptic medicines such as **VIMCOSA** have had thoughts of harming or killing themselves. If you have any of these thoughts at any time, tell your doctor straight away.
- you have a heart problem that affects the beat of your heart and you often have a particularly slow, fast or irregular heart beat (such as AV block, atrial fibrillation and atrial flutter),
- you have severe heart disease such as heart failure or have had a heart attack.
- You are often dizzy or fall over. **VIMCOSA** may make you dizzy - this could increase the risk of accidental injury or a fall. This means that you should take care until you are used to the effects of this medicine.

If you are taking **VIMCOSA**, talk to your doctor if you are experiencing a new type of seizure or worsening of existing seizures.
If you are taking **VIMCOSA** and you are experiencing symptoms of abnormal heartbeat (such as slow, rapid or irregular heartbeat, palpitations, shortness of breath, feeling lightheaded, fainting), seek medical advice immediately (see section 4).

**Children**
**VIMCOSA** is not recommended for children aged under 2 years with epilepsy characterised by the occurrence of partial-onset seizure and not recommended for children aged under 4 years with primary generalized tonic-clonic seizures. This is because we do not yet know whether it will work and whether it is safe for children in this age group.

**Other medicines and VIMCOSA**
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:
- medicines to treat heart problems;
- medicines which can increase the "PR interval" on a scan of the heart (ECG or electrocardiogram) such as medicines for epilepsy or pain called carbamazepine, lamotrigine or pregabalin;
- Medicines used to treat certain types of irregular heart beat or heart failure.

Also tell your doctor or pharmacist if you are taking any of the following medicines - this is because they may increase or decrease the effect of **VIMCOSA** on your body:
- medicines for fungal infections such as fluconazole, itraconazole or ketoconazole;
- medicines for HIV such as ritonavir;
- medicines used to treat bacterial infections such as clarithromycin or rifampicin;
- a herbal medicine used to treat mild anxiety and depression called St. John's wort.

**VIMCOSA with food and drink:**
**VIMCOSA** should be taken with or without food.

**Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **VIMCOSA.**
It is not recommended to use **VIMCOSA** if you are pregnant.
It is not recommended to use **VIMCOSA** if you are breastfeeding your baby.

**Driving and using machines**
Do not drive or use machines until you know how **VIMCOSA** affects you. **VIMCOSA** can cause dizziness or blurred vision.

**3. How to take VIMCOSA**

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

Always take **VIMCOSA** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
**VIMCOSA** must be taken twice daily twelve hours apart. Tablets should be taken whole.

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

**If you take more VIMCOSA 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 VIMCOSA**
It is important to take your **VIMCOSA** 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 two doses at the same time, to make up for a missed dose.

**If you stop taking VIMCOSA**
If **VIMCOSA** is stopped earlier than your doctor has prescribed, your symptoms of may return or worsen. Always take **VIMCOSA** for as long as your doctor has prescribed.

**4. Possible side effects**

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

If any of the following happens, stop taking **VIMCOSA** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- If you start to get flu-like symptoms with a painful rash affecting the top layer of your skin.
- If you experience a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens–Johnson syndrome), and a more severe form causing skin peeling in more than 30 % of the body surface (toxic epidermal necrolysis);

These are all very serious side effects. If you have them, you may have had a serious reaction to **VIMCOSA**. You may need urgent medical attention or hospitalisation.

**Tell your doctor if you notice any of the following:**
*Frequently occurring:*
- Headache
- Dizziness
- Double vision
- Short jerks of a muscle or group of muscles (myoclonic seizures);
- Difficulties in coordinating your movements or walking;
- Problems in keeping your balance, shaking (tremor), tingling (paresthesia) or muscle spasms, falling easily and getting bruises;
- Troubles with your memory, thinking or finding words, confusion;
- Rapid and uncontrollable movements of the eyes (nystagmus), blurred vision;
- A spinning sensation (vertigo), feeling drunk;
- Being sick (vomiting), dry mouth, constipation, indigestion, excessive gas in the stomach or bowel, diarrhoea;
- Decreased feeling or sensitivity, difficulty in articulating words, disturbance in attention;
- Noise in the ear such as buzzing, ringing or whistling;
- Irritability, trouble sleeping, depression;
- Sleepiness, tiredness or weakness (asthenia);
- Itching, rash

**Less frequently occurring**:
- Slow heart rate, palpitations, irregular pulse or other changes in the electrical activity of your heart (conduction disorder);
- Exaggerated feeling of wellbeing, seeing and/or hearing things which are not there;
- Allergic reaction to medicine intake, hives;
- Blood tests may show abnormal liver function, liver injury;
- Thoughts of harming or killing yourself or attempting suicide: tell your doctor straight away;
- Feeling angry or agitated;
- Abnormal thinking or losing touch with reality;
- Serious allergic reaction which causes swelling of the face, throat, hands, feet, ankles, or lower legs;
- Fainting;
- Abnormal involuntary movements (dyskinesia).

**Frequency unknown**
- Abnormal rapid heartbeat (ventricular tachyarrhythmia);
- A sore throat, high temperature and getting more infections than usual. Blood tests may show a severe decrease in a specific class of white blood cells (agranulocytosis);
- A serious skin reaction which may include a high temperature and other flu-like symptoms, a rash on the face, extended rash, swollen glands (enlarged lymph nodes). Blood tests may show increased levels of liver enzymes and a type of white blood cell (eosinophilia);
- Convulsions

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 **VIMCOSA**, please consult your healthcare provider for advice.

**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 **VIMCOSA.**

**5. How to store VIMCOSA**

Store at or below 25 °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 VIMCOSA contains**
The active ingredient is lacosamide.
Sugar-Free

**Tablet core**
Microcrystalline cellulose
Crospovidone Type A
Colloidal silicon dioxide
Low substituted hydroxypropyl cellulose
Hydroxy propyl cellulose
Magnesium stearate
**Tablet coat**
Opadry II Pink, Opadry II Yellow, Opadry II Beige, Opadry II Blue
**Film-coat:** HPMC 2910/Hypromellose (6mPas) (E 464), HPMC 2910/Hypromellose (15mPas) (E 464), polyvinyl alcohol – part hydrolyzed, talc (E 553b), titanium dioxide (E171), Macrogol/PEG (MW 3350, Macrogol 4000), Lecithin (Soya)
**Colourants***
***The colourants are:**
**50 mg tablet:** red iron oxide (E172), black iron oxide (E172).
**100 mg tablet:** yellow iron oxide (E172).
**150 mg tablet:** yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172).
**200 mg tablet:** indigo carmine aluminium lake (E132).

**What VIMCOSA looks like and contents of the pack**
**VIMCOSA 50 mg:** Pink coloured, biconvex, oval shaped, film-coated tablets debossed with "L50" on one side and plain on other side.
**VIMCOSA 100 mg:** Yellow coloured, biconvex, oval shaped, film-coated tablets debossed with "L100" on one side and plain on other side.
**VIMCOSA 150 mg:** Salmon coloured, biconvex, oval shaped, film-coated tablets debossed with "L150" on one side and plain on other side.
**VIMCOSA 200 mg:** Blue coloured, biconvex, oval shaped, film coated tablets debossed with "L200" on one side and plain on other side.

**Contents of the pack:**
Packs of 14, 28, 30, 56, 60, 98 and 168 film-coated tablets in PVC/PVDC blister sealed with an aluminium foil.

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, SOUTH AFRICA



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**Registration numbers**
**VIMCOSA 50 mg:** 57/2.5/0717.713
**VIMCOSA 100 mg:** 57/2.5/0718.714
**VIMCOSA 150 mg:** 57/2.5/0719.715
**VIMCOSA 200 mg:** 57/2.5/0720.716


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

**VIMCOSA**
**50/100/150/200**
**(film-coated tablet)**
PM04272301

320 mm

335 mm

# Back Side

320 mm

**PASIËNTINLIGTINGSTUK**

**SKEDULERINGSTATUS:** S3

**VIMCOSA 50 mg** (filmbedekte tablet)
**VIMCOSA 100 mg** (filmbedekte tablet)
**VIMCOSA 150 mg** (filmbedekte tablet)
**VIMCOSA 200 mg** (filmbedekte tablet)
Lakosamied
Suikervry

**Lees hierdie inligtingstuk sorgvuldig deur voordat jy VIMCOSA 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
- **VIMCOSA** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

**Wat is in hierdie inligtingstuk**

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


## 1. Wat VIMCOSA is en waarvoor dit gebruik word

**VIMCOSA** bevat lakosamied.
Lakosamied behoort aan 'n groep medisyne genaamd "anti-epileptiese medisyne". Hierdie medisyne word gebruik om epilepsie te behandel.

- Hierdie medisyne is aan jou gegee om die aantal stuipe (aanvalle) wat jy kry, te verminder.

**VIMCOSA** word gebruik vir:
kinders, ouderdom 2 jaar en ouer om 'n sekere tipe epilepsie te behandel wat gekenmerk word deur die voorkoms van gedeeltelike aanvangs aanval met of sonder sekondêre veralgemening. In hierdie tipe van epilepsie affekteer aanvalle eerste net een kant van jou brein. Dit kan egter dan na groter areas aan beide kante van jou brein versprei;

in samewerking met ander anti-epileptiese medisyne in volwassenes, adolessente en kinders, ouderdom 4 jaar en ouer om primêre algemene tonies-kloniese aanvalle (erge aanvalle, insluitend verlies van bewussyn) te behandel in pasiënte met idiopatiese veralgemene epilepsie (die tipe epilepsie wat vermoedelik 'n genetiese oorsaak het).

## 2. Wat jy behoort te weet voordat jy VIMCOSA neem

**Moet nie VIMCOSA neem nie:**
- indien jy hipersensitief (allergies) vir lakosamied of enige van die ander bestanddele, gelys in afdeling 6, van hierdie medisyne is nie.
- indien jy 'n sekere tipe hartkloppprobleem het wat tweede- of derdegraadse AV-blok genoem word.

**Waarskuwings en voorsorgmaatreëls**
Praat met jou dokter voordat **VIMCOSA** geneem word

Voordat jy **VIMCOSA** begin neem, vertel vir jou dokter of jy het, of al ooit gehad het:
- Jy het gedagtes om jouself leed aan te doen of dood te maak. Sommige mense wat behandel word met anti-epileptiese medisyne soos **VIMCOSA** het gedagtes gehad om hulself leed aan te doen of dood te maak. As jy te eniger tyd enige van hierdie gedagtes het, moet jy onmiddellik jou dokter vertel.

- jy het 'n hartprobleem wat die klop van jou hart affekteer en jy het dikwels 'n besonder stadige, vinnige of onreëlmatige hartklop, hartkloppings, kort van asem, ligh oofdig voel, flou word), moet jy onmiddellik mediese advies inwin (sien afdeling 4).
- jy het ernstige hartsiektes soos hartversaking of het 'n hartaanval gehad.

- Jy is dikwels duiselig of val om. **VIMCOSA** kan jou duiseliq maak - dit kan die risiko verhoog van toevallige besering of 'n val. Dit beteken dat jy moet spesiale sorg neem, totdat jy gewoond is aan die effekte van hierdie medisyne.

Indien jy **VIMCOSA** neem, praat met jou dokter wanneer jy 'n nuwe tipe aanval of verergering van bestaande aanvalle ervaar.
Indien jy **VIMCOSA** neem en jy simptome van abnormale hartklop ervaar (soos 'n stadige, vinnige of onreëlmatige hartklop, hartkloppings, kort van asem, ligh oofdig voel, flou word), moet jy onmiddellik mediese advies inwin (sien afdeling 4).

**Kinders**
**VIMCOSA** word nie aanbeveel vir kinders jonger as 2 jarige ouderdom met epilepsie wat gekenmerk word deur die voorkoms van gedeeltelike aanvangs aanval nie en word nie aanbeveel vir kinders jonger as 4 jarige ouderdom met primêre algemene tonies-kloniese aanvalle nie. Dit is omdat ons nog nie weet of dit sal werk en of dit veilig is vir kinders in hierdie ouderdomsgroep nie.

**Ander medisyne en VIMCOSA**
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel jou dokter of apteker indien jy enige van die volgende medisyne neem:

- medisyne om hartprobleme te behandel;
- medisyne wat die "PR-interval" kan verhoog op 'n skandering van die hart (EKG of elektrokardiogram) soos medisyne vir epilepsie of pyn naamlik karbamasepien, lamotrigien of pregabalien;
- Medisyne wat gebruik word om sekere tipes onreëlmatige hartklop of hartversaking te behandel.

Vertel ook vir jou dokter of apteker indien jy enige van die volgende medisyne gebruik - dit is omdat hulle die effek van **VIMCOSA** op jou liggaam kan verhoog of verminder:

- medisyne soos flukonasool, itrakonasool of ketokonasool vir swambesmetting;
- medisyne soos ritonavir vir MIV;
- medisyne soos klaritromisien of rifampisien wat gebruik word om bakteriële infeksies te behandel;
- 'n kruiemedisyne wat gebruik word om ligte angs en depressie te behandel, naamlik St Johanneskruid.

**VIMCOSA met voedsel en drank:**
**VIMCOSA** moet met of sonder kos geneem word.

**Swangerskap, borsvoeding en fertiliteit**
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **VIMCOSA** neem

Dit word nie aanbeveel om **VIMCOSA** te gebruik as jy swanger is nie.

Dit word nie aanbeveel **VIMCOSA** te gebruik as jy jou baba borsvoed nie.

**Bestuur en gebruik van masjinerie**
Moet nie bestuur of masjiene gebruik totdat jy weet hoe **VIMCOSA** jou affekteer nie. **VIMCOSA** kan duiseligheid of dowwe visie veroorsaak.

## 3. Hoe om VIMCOSA te neem

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

Neem altyd **VIMCOSA** presies soos jou dokter jou beveel het. Vra vir jou dokter of apteker indien jy onseker is.

**VIMCOSA** moet twee keer per dag, twaalf ure uitmekaar geneem word. Tablette moet heel geneem word.

Indien jy die indruk kry dat die effek van **VIMCOSA** te sterk of te swak is, praat met jou dokter of apteker.

**Indien jy meer VIMCOSA neem as wat jy behoort te neem**
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 VIMCOSA te neem**
Dit is belangrik om jou **VIMCOSA** gereeld op dieselfde tyd elke dag te neem. As jy vergeet om 'n dosis te neem, neem dit sodra jy onthou, tensy dit tyd is vir jou volgende dosis. Moet nie twee dosisse gelyktydig neem om vir 'n vergete dosis op te maak nie.

**Indien jy ophou om VIMCOSA te neem**
Indien **VIMCOSA** vroeër gestaak word as wat jou dokter voorgeskryf het, kan jou simptome terugkeer of vererger. Neem altyd **VIMCOSA** vir solank as wat jou dokter dit voorgeskryf het.

## 4. Moontlike newe-effekte

**VIMCOSA** kan newe-effekte hê.
Nie al die newe-effekte wat vir **VIMCOSA** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige ongewenste effekte ondervind terwyl jy **VIMCOSA** neem, kontak asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om **VIMCOSA** te neem en sê onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:

- Indien jy griepagtige simptome begin kry, met 'n pynlike uitslag wat die boonste laag van jou vel aantas.
- Indien jy 'n wydverspreide uitslag ervaar met blase en afskilfering van die vel, veral rondom die mond, neus, oë en geslagsdele (Stevens–Johnson-sindroom), en 'n meer ernstiger vorm wat velafskilfering in meer as 30 % van die liggaamsoppervlak veroorsaak (toksiese epidermale nekrolise);

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige reaksie teen **VIMCOSA** gehad het. Jy mag dringende mediese aandag of hospitalisering nodig hê.

**Sê vir jou dokter indien jy enige van die volgende waarneem:**
***Kom gereeld voor:***
- Hoofpyn
- Duiseligheid
- Dubbelvisie
- Kort trekkings van 'n spier of groep spiere (miokloniese aanvalle);
- Probleme met die koördinering van jou bewegings of stap;
- Probleme om jou balans te hou, bewing (rilling), tinteling (parestesie) of spierspasmas, val maklik en kry kneusplekke;
- Probleme met jou geheue, denke of vind van woorde, verwarring;
- Vinnige en onbeheerbare bewegings van die oë (nistagmus), dowwe visie;
- 'n Spinsensasie (vertigo), dronk voel;
- Siek wees (braking), droë mond, hardlywigheid, slegte spysvertering, oormatige gas in die maag of derm, diarree;
- Verminderde gevoel of sensitiwiteit, probleme met die artikulasie van woorde, versteuring in aandag;
- Geraas in die oor soos gons, lui of fluit;
- Prikkelbaarheid, probleme om te slaap, depressie;
- Slaperigheid, moegheid of swakheid (astenie);
- Gejeuk, uitslag

***Kom minder gereeld voor:***
- Stadige harttempo, hartkloppings, onreëlmatige polsslag of ander veranderinge in die elektriese aktiwiteit van jou hart (geleidingsversteuring);
- Oordrewe gevoel van welstand, om dinge te sien en/of te hoor wat nie daar is nie;
- Allergiese reaksie op medisyne-inname, galbulte;
- Bloedtoetse kan abnormale lewerfunksie, lewerbesering aandui;
- Gedagtes om jouself leed aan te doen of dood te maak of poging tot selfmoord: vertel onmiddellik jou dokter;
- Kwaad of ontsteld voel;
- Abnormale denke of kontak met die werklikheid verloor;
- Ernstige allergiese reaksie wat swelling van die gesig, keel, hande, voete, enkels of onderbene veroorsaak;
- -Floute;
- Abnormale onwillekeurige bewegings (diskinesie).

***Frekwensie onbekend***
- Abnormale vinnige hartklop (ventrikulêre tagi-aritmie);
- 'n Seer keel, hoë temperatuur en meer infeksies as gewoonlik kry. Bloedtoetse kan 'n ernstige afname in 'n spesifieke klas van witbloedselle (agranulositose) aandui;
- 'n Ernstige velreaksie wat 'n hoë temperatuur en ander griepagtige simptome, 'n uitslag op die gesig, verlengde uitslag, geswelde kliere (vergrote limfknope) kan insluit. Bloedtoetse kan verhoogde vlakke van lewerensieme en 'n tipe van witbloedsel (eosinofiile) aandui;
- Stuiptrekkings

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis.

Sou jou algemene gesondheid verswak of as jy enige ongewenste effekte ervaar terwyl jy **VIMCOSA** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

**Aanmelding van newe-effekte**
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **VIMCOSA**.

## 5. Hoe om VIMCOSA te bewaar

Bewaar by of benede 25°C.
HOU BUITE DIE BEREIK VAN KINDERS.
Stoor in die oorspronklike pak / houer.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat aangebring is op die stulpstroke / etiket / karton / bottel nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

## 6. Inhoud van die pak en ander inligting

**Wat VIMCOSA bevat**
Die aktiewe bestanddeel is lakosamied.
Suikervry
**Tabletkern**
Mikrokristallyne sellulose
Kruspovidoon Tipe A
Kolloïdale silikondioksied
Lae gesubstitueerde hidroksipropielsellulose
Hidroksipropielsellulose
Magnesiumstearaat
**Tabletbedekking**
Ondeursigtige II Pienk, Ondeursigtige II Geel, Ondeursigtige II roomkleurige, Ondeursigtige II Blou
**Filmbedekking:** HPMC 2910/Hipromellose (6mPas) (E 464), HPMC 2910/Hipromellose (15mPas) (E 464), poliviniielalkohol – gedeeltelik gehidroliseer, talkum (E 553b), titaandioksied (E171), Makrogol/PEG (MW 3350, Makrogol 4 000), Lesitien (Soja)

**Kleurmiddels***
***Die kleurmiddels is:**
**50 mg tablet:** rooi ysteroksied (E172), swart ysteroksied (E172).
**100 mg tablet:** geel ysteroksied (E172).
**150 mg tablet:** geel ysteroksied (E172), rooi ysteroksied (E172), swart ysteroksied (E172).
**200 mg tablet:** indigo karmyn aluminium meer (E132).

**Hoe VIMCOSA lyk en inhoud van die pak**
**VIMCOSA 50 mg:** Pienkkleurige, bikonvekse, ovaalvormige, filmbedekte tablette gestempel met "L50" aan die een kant en glad aan die ander kant.
**VIMCOSA 100 mg:** Geelkleurige, bikonvekse, ovaalvormige, filmbedekte tablette gestempel met "L100" aan die een kant en glad aan die ander kant.
**VIMCOSA 150 mg:** Salmkleurige, bikonvekse, ovaalvormige, filmbedekte tablette gestempel met "L150" aan die een kant en glad aan die ander kant.
**VIMCOSA 200 mg:** Bloukleurige, bikonveks, ovaalvormig, filmbedekte tablette gestempel met 'L200" aan die een kant en glad aan die ander kant.

**Inhoud van die pak:**
Verpakkings van 14, 28, 30, 56, 60, 98 en 168 filmbedekte tablette in PVC/PVDC stulpstroke verseël met 'n aluminiumfoelie.

Nie alle verpakkingsgroottes word bemark nie.

## 7. Houer van die Registrasiesertifikaat

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

**Hierdie inligtingstuk was laas hersien in**
12 Desember 2023

**Registrasienommers**
**VIMCOSA 50 mg:** 57/2.5/0717.713
**VIMCOSA 100 mg:** 57/2.5/0718.714
**VIMCOSA 150 mg:** 57/2.5/0719.715
**VIMCOSA 200 mg:** 57/2.5/0720.716

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

335 mm

MASTER COPY

MACLEODS

*Restricted Circulation*

PACKAGING RESEARCH & DEVELOPMENT

(Front Page)

## ARTWORK / PRINTPROOF APPROVAL FORM

| | |
|---|---|
| 1. Product: VIMCOSA 50/100/150/200 ( Lacosamide Tablets 50/100/150/200 mg ) | |
| 2. Country: South Africa ( Private Market ) | 3. Packaging component: Patient Information Leaflet |
| 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 320 (W) mm |
| 9. Design / Style: Booklet | 10. Item code No.: PM04272301 |
| 11. Artwork has been made: Actual Size | 12. Pharma code No.: 33424 mini |
| 13. Barcode/NDC no: NA | 14. Supersedes Item code No: NA |
| 15. Revision No: 00 | 16. A/W File name:Z:\LACOSAMIDE TABLETS\01\LACOSAMIDE TABLETS PIL - PM04272301.cdr |
| Approved By: | 17. Location: Baddi |

| PRD | M.A. HOLDER | RAD | QC | PRODN | QA |
|---|---|---|---|---|---|
| 23/01/24 | Vanita Rajool | 17/01/24 | 25/01/24 | 23/01/24 | 25/01/24 |

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

25/01/24

**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 - Private Market | PM04272301 | | |

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