Front Side

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S5

GLOVIREG 25 Capsules
Pregabalin
Contains Sugar – lactose monohydrate (35 mg)

GLOVIREG 75 Capsules
Pregabalin
Contains Sugar – lactose monohydrate (8,25 mg)

GLOVIREG 150 Capsules
Pregabalin
Contains Sugar – lactose monohydrate (16,50 mg)

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

1. What GLOVIREG is and what it is used for

GLOVIREG is used to treat peripheral neuropathic pain (long-lasting pain caused by damage to the nerves), due to diabetes or shingles in adults.

2. What you need to know before you take GLOVIREG

Do not take GLOVIREG:
- If you are allergic (hypersensitive) to pregabalin or any of the other ingredients of **GLOVIREG** (listed in **section 6**).

Warnings and precautions
Take special care with GLOVIREG:
- If you have diabetes and gain weight while you are taking **GLOVIREG**, your doctor may need to make a change in your diabetic medicines.
- If you experience an allergic reaction while you are taking **GLOVIREG**, you must contact your doctor immediately. The symptoms of an allergic reaction include swelling of the face, lips, tongue, and throat, as well as a skin rash.
- If you take **GLOVIREG** you may experience dizziness, sleepiness, loss of consciousness, confusion, and mental impairment. This could increase the possibility of an accidental injury (fall) if you are an elderly patient. Therefore, you should be careful until you are used to any effect caused by **GLOVIREG**.
- If you take **GLOVIREG** you may experience blurring or loss of vision, or other changes in eyesight, many of which are temporary. You should immediately tell your doctor if you experience any changes in your vision.
- If you notice a decrease in passing urine while taking **GLOVIREG**, you should tell your doctor. It may improve if you stop taking **GLOVIREG.**
- If you are taking **GLOVIREG**, or shortly after stopping it, you may experience convulsions (including epilepsy). If this happens, contact your doctor immediately. You may also experience withdrawal symptoms after short-term or long-term treatment with **GLOVIREG**, which include difficulty in sleeping, headache, nausea, anxiety, diarrhoea, flu syndrome, nervousness, depression, pain, hyperhidrosis and dizziness.
- If you have a history of a heart disease you should tell your doctor. Heart failure has been reported in some patients when they were taking **GLOVIREG**.
- If you are taking medicines for spinal cord injury, you may experience an increase in certain side effects such as sleepiness, when you are also taking **GLOVIREG**.
- Some people have had thoughts to harm or kill themselves while taking medicines belonging to the same group as **GLOVIREG** for the treatment of different conditions. If you have thoughts of harming or killing yourself, at any time when you are taking **GLOVIREG**, immediately contact your doctor.
- When **GLOVIREG** is taken with other medicines that may cause constipation (such as some types of pain medicines) it is possible that gastrointestinal problems may occur (e.g. constipation, blocked or paralysed bowel). Tell your doctor if you experience constipation, especially if you are prone to this problem.
- If you have a history of alcoholism or substance abuse or dependence, you should tell your doctor. If you think you need more **GLOVIREG** than prescribed, tell your doctor.
- If you have a history of any serious medical conditions you should tell your doctor. There have been reports of reduction in brain function (encephalopathy) in some patients when they were taking **GLOVIREG**.
- If you take **GLOVIREG** with medicines that are used to treat depression, you may experience respiratory failure (symptoms include difficulty breathing or shortness of breath, especially when active, coughing up mucous, wheezing and rapid breathing).
- If you use opioids (medicines used to treat pain such as morphine, codeine, oxycodone) together with **GLOVIREG**, you may experience respiratory depression which presents as slow or shallow breathing.
- There have been reports of breathing difficulties with **GLOVIREG**. If you have nervous system disorders, respiratory (breathing) disorders, renal (kidney) impairment, or you are older than 65, your doctor may prescribe a different dosing regimen for you. Contact your doctor if you experience trouble breathing or shallow breaths.

If you are not sure whether any of the above applies to you, ask your pharmacist or your doctor.

Other medicines and GLOVIREG
Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).
GLOVIREG and certain other medicines may influence each other (interaction). When taken with certain other medicines, **GLOVIREG** may potentiate the side effects seen with these medicines, including respiratory failure and coma. The degree of dizziness, sleepiness and decreased concentration may be increased if **GLOVIREG** is taken together with medicines containing:
- Oxycodone (for treatment of pain)
- Lorazepam (for treatment of anxiety)
- Alcohol

GLOVIREG may be taken with oral contraceptives.

GLOVIREG with food, drink and alcohol
GLOVIREG may be taken with or without food.
It is advised not to drink alcohol while you are taking **GLOVIREG.**

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking **GLOVIREG**.
GLOVIREG should not be taken during pregnancy or when breastfeeding. Effective contraception must be used by women of child-bearing potential.

Driving and using machines
GLOVIREG may cause dizziness, sleepiness and decreased concentration. Head and body injuries and road traffic incidents have also been reported with **GLOVIREG.** You should not drive, operate machinery or engage in other potentially hazardous activities until you know whether **GLOVIREG** affects your ability to perform these activities.

GLOVIREG contains lactose
If you have been told by your doctor that you have a rare hereditary problem of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption you should not use this medicine.

3. How to take GLOVIREG

Do not share medicines prescribed for you with any other person.
Always take **GLOVIREG** exactly as your doctor has told you. Check with your doctor if you are not sure.
Your doctor will determine what dose is appropriate for you.

The usual dose is: 75 mg twice daily, (150 mg/day), with or without food. Based on individual patient response and tolerability, the dose may be increased to 150 mg twice daily after an interval of 3 to 7 days.

GLOVIREG is a long-term treatment and you may need to take it for some time. Your doctor will tell you how long your treatment with **GLOVIREG** will last.

GLOVIREG is for oral use only. **GLOVIREG** is taken orally with or without food. Swallow the capsule whole with water.

If you have the impression that the effect of **GLOVIREG** is too strong or too weak, tell your doctor or pharmacist.

Children and adolescents:
The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore **GLOVIREG** should not be given to patients in this age group.

Kidney disorders:
Your doctor may prescribe a different dosing schedule and/or dose.

Elderly patients:
If you are an elderly patient (over 65 years of age), you should take **GLOVIREG** normally except if you have problems with your kidneys. Discuss with your doctor.

If you take more GLOVIREG than you should
In the event of overdosage, consult your doctor or pharmacist, if neither is available, contact the nearest hospital or poison centre. You may feel sleepy, confused, agitated, or restless as a result of taking more **GLOVIREG** than you should. Fits have also been reported.

If you forget to take GLOVIREG
It is important to take your **GLOVIREG** capsules 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. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with GLOVIREG is stopped
Do not stop taking **GLOVIREG** unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of one week.

4. Possible side effects

GLOVIREG can have side effects.
Not all side effects reported for **GLOVIREG** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **GLOVIREG**, please consult your doctor, pharmacist or other healthcare professional for advice.
Patients and caregivers should seek medical attention immediately if someone experiences symptoms of respiratory problems, because these can be life-threatening. Symptoms to watch for include:
- Confusion
- Unusual dizziness or lightheadedness
- Extreme sleepiness or lethargy
- Slowed, shallow or difficult breathing
- Unresponsiveness, which means a person does not answer or react normally or you cannot wake them up
- Bluish-colored or tinted skin, especially on the lips, fingers and toes.

If any of the following happens, stop taking **GLOVIREG** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to **GLOVIREG**. 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:
- heart disorders including heart failure, heart rhythm disturbances, such as increased heart rate, irregular heartbeat,
- an extremely severe skin reaction with rash, ulcers or blisters on the skin (Stevens-Johnson syndrome),
- inflammation of the eyes (keratitis),
- urinary incontinence, difficulty in passing urine, kidney failure, passing small amounts of urine, urinary retention,
- inflammation of the liver (hepatitis),
- yellowing of the skin and eyes (jaundice).

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

Tell your doctor if you notice any of the following:
Frequent:
- inflammation of nasal passages (common cold),
- increased appetite,
- feeling of elation, confusion, irritability, disorientation, sleeplessness, and changes in sexual interest,
- dizziness, sleepiness, headache,
- clumsiness, tremor, difficulty with speaking, forgetfulness, loss of memory, disturbance in attention, numbness or 'pins and needles', abnormally decreased sensitivity to stimulation,
- sedation, abnormal style of walking (balance disorder), lack of energy,
- blurred vision, double vision,
- sensation of movement,
- vomiting, nausea, constipation, diarrhoea, feeling bloated, abdominal distension, dry mouth,
- muscle cramp, pain in a joint, back pain, pain in a limb, cervical spasm,
- difficulties with erection,
- swelling of feet and lower legs caused by fluid retention, abnormal manner of walking, falling, feeling drunk, abnormal feeling, tiredness,
- weight gain.

Less frequent:
- reduced numbers of white blood cells which may make you more likely to get infections (neutropaenia),
- loss of appetite, low blood sugar,
- seeing or hearing things that are not there, panic attacks, restlessness, exceeding restlessness, depression, depressed mood, elevated mood, aggression, mood swings, change in perception of self (depersonalisation), difficulty speaking, abnormal dreams, lack of feeling or emotion, loss of inhibition,
- fainting, numbness, contraction of a muscle, loss of consciousness, jerky movements, difficulty of movement, dizziness on standing, tremor on movement, unusual eye movement, decreased consciousness, difficulty with thinking, speech disorder, reduced reflexes, increased sensitiveness of the skin, burning sensation, loss of taste, feeling of bodily discomfort, convulsions, perversion of the sense of smell, partial or complete loss of muscle movement, inability to write coherently, as a symptom of brain disease or damage,
- vision loss, peripheral vision loss, visual disturbance, eye swelling, visual field defect, reduced visual sharpness, eye pain, eye condition that manifests itself through nonspecific symptoms such as fatigue, pain in or around the eyes, the presence of flashes of light, dry eye, watery eyes, eye irritation,
- visual field disturbance, altered visual depth perception, abnormal dilation of the pupil, squinting of eye(s), visual brightness,
- increased sensitivity to sound,
- low blood pressure, high blood pressure, hot flushes, redness of the neck and face, feeling cold,
- shortness of breath, nosebleed, cough, blocked nose, runny nose, snoring, nasal dryness, fluid in the lungs, tightness of the throat,
- respiratory depression – slow and shallow breathing,
- heartburn, increased saliva production, numbness around the mouth, abdominal swelling, inflammation of the pancreas, swollen tongue, difficulty in swallowing,
- hives, excessive sweating, itching of the skin, cold sweat,
- joint swelling, pain in a muscle or muscles, muscle twitching, neck pain, muscle stiffness, breakdown of muscle tissue,
- problems with sexual functioning including inability to achieve a sexual climax, increased libido, difficulties with erection, delayed ejaculation, painful menstrual periods, breast pain, absence of menstrual period, breast discharge, breast enlargement, breast enlargement in men,
- generalised swelling caused by fluid retention, swelling of the face, chest tightness, pain, fever, thirst, chills, weakness,
- changes in blood and liver test results (increased blood creatinine phosphokinase, increased alanine amino transferase, increased blood glucose, increased aspartate aminotransferase, decreased platelet count, increased blood creatinine, decreased blood potassium, decreased white blood cell count).

Unknown frequency:
- thoughts of harming or killing one-self.

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, pharmacist or nurse.
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 **GLOVIREG**.

5. How to store GLOVIREG

KEEP OUT OF THE REACH OF CHILDREN.
Store at or below 25 °C (room temperature). Protect from light.
Store in the original package/container.
Keep the blisters in the carton until required for use.
Do not store in bathroom.
Keep the container tightly closed.
Do not use after the expiry date stated on the bottle / carton / 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 GLOVIREG contains
The active ingredient is pregabalin.
The other ingredients are**:**
Lactose monohydrate, pregelatinised starch and talc. Hard gelatin capsule containing,
GLOVIREG 25 contains: gelatin, sodium lauryl sulphate and titanium dioxide.
GLOVIREG 75 contains: gelatin, sodium lauryl sulphate, titanium dioxide and red iron oxide.
GLOVIREG 150 contains: gelatin, sodium lauryl sulphate and titanium dioxide.
Contains sugar: lactose monohydrate.
GLOVIREG 25 contains 35 mg lactose monohydrate per capsule.
GLOVIREG 75 contains 8,25 mg lactose monohydrate per capsule.
GLOVIREG 150 contains 16,50 mg lactose monohydrate per capsule.

What GLOVIREG looks like and contents of the pack
GLOVIREG 25: White/white, size '4' hard gelatin capsules imprinted with 'M1' on cap and '25 mg' on body containing white colored powder.

GLOVIREG 75: Brown/white, size '4' hard gelatin capsules imprinted with 'M3' on cap and '75 mg' on body containing white colored powder.

GLOVIREG 150: White/white, size '2' hard gelatin capsules imprinted with 'M5' on cap and '150 mg' on body containing white colored powder.

Contents of the pack:
Blister Pack:
25 µ Aluminium foil/ 6-8 gsm HSL as the lidding material and clear, PVC/PVdC film, 250 µ PVC/90 gsm PVdC as the forming material.
Pack size include 14's, 56's, 60's or 100's capsules
HDPE Container Pack:
Round, white HDPE container with screw neck with white child-resistant closure with pulp and heat seal liner.
Pack size 90 capsules
* Not all pack sizes may be marketed.

7. Holder of Certificate of Registration

MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.
Tel: +27 11 682 11 69

8. This leaflet was last revised in

03 September 2024

9. Registration numbers

GLOVIREG 25: 48/2.5/1109
GLOVIREG 75: 48/2.5/1110
GLOVIREG 150: 48/2.5/1111

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

GLOVIREG 25/75/150
PM04340157

300 mm

335 mm

Back Side

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S5

GLOVIREG 25 Kapsules
Pregabalin
Bevat suiker – laktosemonohidraat (35 mg)

GLOVIREG 75 Kapsules
Pregabalin
Bevat suiker –laktosemonohidraat (8,25 mg)

GLOVIREG 150 Kapsules
Pregabalin
Bevat suiker –laktosemonohidraat (16,50 mg)

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy GLOVIREG begin gebruik
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het.
- **GLOVIREG** 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 in hierdie inligtingstuk is

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

1. Wat GLOVIREG is en waarvoor dit gebruik word

GLOVIREG word gebruik vir die behandeling van periferiese neuropatiese pyn (langdurige pyn veroorsaak deur skade aan die senuwees), as gevolg van diabetes of gordelroos in volwassenes.

2. Wat jy behoort te weet voordat jy GLOVIREG neem

Moet nie GLOVIREG neem nie:
- Indien jy allergies (hipersensitief) is vir pregabalin of enige van die ander bestanddele van **GLOVIREG** (gelys in **afdeling 6.1**).

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met GLOVIREG:
- Indien jy diabetes het en jou gewig toeneem terwyl jy **GLOVIREG** gebruik, sal jou dokter moontlik 'n verandering in jou diabetiese medisyne moet maak.
- Indien jy 'n allergiese reaksie ervaar terwyl jy **GLOVIREG** gebruik, moet jy onmiddellik jou dokter kontak. Die simptome van 'n allergiese reaksie sluit in swelling van die gesig, lippe, tong en keel, asook 'n veluitslag.
- Indien jy **GLOVIREG** neem, kan jy duiseligheid, slaperigheid, bewussynsverlies, verwarring en geestesinkorting ervaar. Indien jy 'n bejaarde pasiënt is kan dit die moontlikheid van 'n toevallige besering (val) verhoog. Jy moet dus versigtig wees, totdat jy gewoond is aan enige effek wat deur **GLOVIREG** veroorsaak word.
- Indien jy **GLOVIREG** neem, kan jy dowwe- of verlies van visie, of ander veranderinge in jou sig ervaar, waarvan meeste tydelik is. Jy moet dadelik jou dokter inlig as jy enige veranderinge in jou visie waarneem.
- Indien jy bewus word van verminderde uriene wat passeer word terwyl jy **GLOVIREG** neem, moet jy jou dokter daarvan vertel. Dit kan verbeter wanneer jy staak om **GLOVIREG** te neem.
- Indien jy **GLOVIREG** neem, of kort nadat jy dit gestaak het, kan jy stuiptrekkings ervaar (insluitend epilepsie). Kontak jou dokter onmiddellik wanneer dit gebeur. Jy kan ook onttrekkingsimptome ervaar na korttermyn- of langtermyn behandeling met **GLOVIREG**, wat probleme met slaap, hoofpyn, naarheid, angstigheid, diaree, griepsindroom, senuweeagtigheid, depressie, pyn, verhoogde sweet afskeiding en duiseligheid insluit.
- Vertel asseblief jou dokter indien jy 'n geskiedenis van 'n hartsiekte het. Hartversaking is in sommige pasiënte aangemeld wanneer hulle **GLOVIREG** gebruik het.
- Indien jy medisyne vir spinale koord besering gebruik, terwyl jy ook **GLOVIREG** neem, kan jy 'n toename in sekere newe-effekte soos slaperigheid ervaar.
- Sommige mense het gedagtes van selfbeskadiging of selfmoord gehad terwyl hulle medisyne gebruik het wat aan dieselfde groep as **GLOVIREG** behoort het vir die behandeling van ander toestande. Kontak onmiddellik jou dokter indien jy gedagtes het om jouself te beseer of jouself dood te maak te eniger tyd terwyl jy **GLOVIREG** neem.
- Wanneer **GLOVIREG** saam met ander medisyne geneem word wat hardlywigheid kan veroorsaak (soos sommige tipes pynmedisyne), is dit moontlik dat gastroïntestinale probleme kan voorkom (bv. hardlywigheid, verstopte of verlamde derm). Vertel jou dokter as jy hardlywigheid ervaar, veral as jy geneig is tot hierdie probleem.
- Indien jy 'n geskiedenis van alkoholisme of dwelmmisbruik of afhanklikheid het, behoort jy jou dokter te vertel. Indien jy dink jy benodig meer **GLOVIREG** as wat voorgeskryf is, raadpleeg jou dokter.
- Indien jy 'n geskiedenis van enige ernstige mediese toestande het, moet jy jou dokter vertel. Daar was berigte van vermindering in breinfunksie (enkefalopatie) in sommige pasiënte wanneer hulle **GLOVIREG** geneem het.
- Indien jy **GLOVIREG** neem saam met medisyne wat gebruik word om depressie te behandel, kan jy respiratoriese versaking ervaar (simptome sluit in moeilike asemhaling of kort van asem, veral wanneer aktief is, ophoes van slym, asemgefluit en vinnige asemhaling).
- Indien jy opioïede (medisyne wat gebruik word om pyn te behandel soos morfien, kodeïen, oksikodoon) saam met **GLOVIREG** gebruik, kan jy respiratoriese onderdrukking ervaar wat presenteer as stadige of vlak asemhaling.
- Daar was al berigte van asemhalingsprobleme met **GLOVIREG**. Indien jy senuweestelselafwykings, respiratoriese (asemhalings) afwykings, renale (nier) inkorting het, of jy ouer as 65 is, kan jou dokter 'n ander doserings regime vir jou voorskryf. Kontak jou dokter indien jy probleme met asemhaling of vlak asemhaling ervaar.

Indien jy nie seker is of enige van die bogenoemde op jou van toepassing is nie, vra jou apteker of jou dokter.

Ander medisyne en GLOVIREG
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
GLOVIREG en sekere ander medisyne kan mekaar beïnvloed (interaksie). **GLOVIREG** kan wanneer dit saam met sekere ander medisyne geneem word, die newe-effekte wat met hierdie medisyne gesien word insluitend respiratoriese versaking en koma, versterk. Die mate van duiseligheid, slaperigheid en verminderde konsentrasie kan verhoog word as **GLOVIREG** saam met medisyne geneem word wat die volgende bevat:
- Oksikodoon (vir behandeling van pyn)
- Lorasepam (vir behandeling van angs)
- Alkohol

GLOVIREG kan saam met orale voorbehoedmiddels geneem word.

GLOVIREG met voedsel, drank en alkohol
GLOVIREG kan met of sonder kos geneem word.
Die inname van alkohol terwyl jy **GLOVIREG** gebruik, word nie aanbeveel nie.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, vermoed dat jy moontlik swanger kan wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy **GLOVIREG** neem.
GLOVIREG moet nie tydens swangerskap of terwyl jy borsvoed, geneem word nie. Effektiewe voorbehoedmiddels moet deur vrouens van kinderbarende potensiaal gebruik word.

Bestuur en gebruik van masjiene
GLOVIREG kan duiseligheid, slaperigheid en verminderde konsentrasie veroorsaak. Kop- en lyfbeserings en padverkeersvoorvalle is ook met **GLOVIREG** aangemeld. Jy moet nie bestuur, masjinerie hanteer of aan ander potensieel gevaarlike aktiwiteite deelneem nie, totdat jy weet of **GLOVIREG** jou vermoë om hierdie aktiwiteite uit te voer, beïnvloed.

GLOVIREG bevat laktose
Indien jy deur jou dokter ingelig is dat jy 'n seldsame oorerflike probleem van galaktose-intoleransie, Lapp-laktasetekort of glukose-galaktose wanabsorpsie het, moet jy nie hierdie medisyne gebruik nie.

3. Hoe om GLOVIREG te gebruik

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **GLOVIREG** presies soos jou dokter jou beveel het. Raadpleeg jou dokter indien jy nie seker is nie.
Jou dokter sal bepaal watter dosis vir jou geskik is.

Die gewone dosis is: 75 mg twee keer per dag, (150 mg/dag), met of sonder kos. Gebaseer op individuele pasiëntreaksie en verdraagsaamheid, kan die dosis verhoog word tot 150 mg twee keer per dag na 'n interval van 3 tot 7 dae.

GLOVIREG is 'n langtermynbehandeling en jy sal dit moontlik vir 'n geruime tyd moet neem. Jou dokter sal vir jou sê hoe lank jou behandeling met **GLOVIREG** sal duur.

GLOVIREG is slegs vir mondelingse gebruik. **GLOVIREG** word oraal, met of sonder kos geneem. Sluk die kapsule heel met water.

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

Kinders en adolessente:
Die veiligheid en doeltreffendheid in kinders en adolessente (jonger as 18 jaar oud) is nie vasgestel nie en daarom moet **GLOVIREG** nie aan pasiënte in hierdie ouderdomsgroep gegee word nie.

Nier versteurings:
Jou dokter mag 'n ander doseringskedule en/of dosis voorskryf.

Bejaarde pasiënte:
Indien jy 'n bejaarde pasiënt is (ouer as 65 jaar oud), moet jy **GLOVIREG** soos normaalweg neem, behalwe as jy probleme met jou niere het. Bespreek dit met jou dokter.

Indien jy meer GLOVIREG 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. Jy mag slaperig, verward, ontsteld of rusteloos voel as gevolg van die neem van meer **GLOVIREG** as wat jy moet. Aanvalle is ook al aangemeld.

Indien jy vergeet om GLOVIREG te neem
Dit is belangrik om jou **GLOVIREG** kapsules gereeld, op dieselfde tyd van elke dag te neem. Indien jy vergeet om 'n dosis te neem, neem dit sodra jy daarvan onthou, tensy dit tyd is vir jou volgende dosering. In so 'n geval, gaan net aan met die volgende dosering soos normaalweg. Moet nie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

Effekte wanneer behandeling met GLOVIREG gestaak word
Moet nie ophou om **GLOVIREG** te neem nie, tensy jou dokter jou beveel om dit te doen. Indien jou behandeling gestaak word, behoort dit geleidelik gedoen te word oor 'n minimum tydperk van een week.

4. Moontlike newe-effekte

GLOVIREG kan newe-effekte hê.
Nie al die newe-effkte wat vir **GLOVIREG** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of indien jy enige ongewenste effekte ondervind terwyl jy **GLOVIREG** gebruik, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.
Pasiënte en versorgers moet onmiddellik mediese hulp soek indien iemand simptome van respiratoriese probleme ervaar, aangesien dit lewensgevaarlik kan wees. Simptome om voor op te let, sluit in:
- Verwarring
- Ongewone duiseligheid of lighoofdigheid
- Uiterste slaperigheid of lusteloosheid
- Stadige, vlak of moeilike asemhaling
- Onreaktiwiteit, wat beteken dat 'n persoon nie normaal reageer of antwoord nie, of jy kan hulle nie wakker kry nie
- Blou kleurige of getinte vel, veral op die lippe, vingers en tone.

Indien enige van die volgende gebeur, staak die gebruik van **GLOVIREG** en vertel onmiddellik jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme met sluk of asemhaling kan veroorsaak,
- uitslag of jeuk.

Al hierdie newe-effekte is baie ernstig. Indien jy dit ervaar, het jy moontlik 'n ernstige reaksie op **GLOVIREG** gehad. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- hart versteurings insluitend hartversaking, hartritme versteurings, soos 'n verhoogde harttempo, onreëlmatige hartklop,
- 'n uiters ernstige velreaksie met uitslag, sere of blase op die vel (Stevens-Johnson sindroom),
- ontsteking van die oë (keratitis),
- urinêre inkontinensie, probleme met urinering, nierversaking, passeer klein hoeveelheid uriene, urinêre retensie,
- ontsteking van die lewer (hepatitis),
- vergeling van die vel en oë (geelsug).

Al hierdie newe-effekte is ernstig. Jy mag dringende mediese aandag benodig.

Lig jou dokter in indien jy enige van die volgende opmerk:
Gereeld:
- ontsteking van neusgange (algemene verkoue),
- verhoogde eetlus,
- gevoel van uitgelatenheid, verwarring, liggeraaktheid, disoriëntasie, slapeloosheid en veranderinge in seksuele belangstelling,
- duiseligheid, slaperigheid, hoofpyn,
- lompheid, bewing, probleme met spraak, vergeetagtigheid, geheueverlies, aandag versteuring, gevoelloosheid of 'spelde en naalde', abnormale verminderde sensitiwiteit vir stimulasie,
- kalmering, abnormale manier van loop (balans versteuring), gebrek aan energie,
- dowwe visie, dubbelvisie,
- sensasie van beweging,
- braking, naarheid, hardlywigheid, diaree, voel opgeblase, abdominale opswelling, droë mond,
- spierkrampe, pyn in 'n gewrig, rugpyn, pyn in 'n ledemaat, servikale spasma,
- probleme met ereksie,
- swelling van voete en onderbene veroorsaak deur vloeistofretensie, abnormale manier van loop, val, voel dronk, voel abnormaal, moegheid,
- toename in gewig.

Minder gereeld:
- verminderde aantal van witbloedselle wat jou meer geneig kan maak om infeksies te kry (neutropenie),
- verlies aan eetlus, lae bloedsuiker,
- dinge sien of hoor wat nie bestaan nie, paniekaanvalle, rusteloosheid, oormatige rusteloosheid, depressie, depressiewe bui, opgewekte bui, aggressie, gemoedstoestand skommelings, verandering in persepsie van self (depersonalisering), probleme om te praat, abnormale drome, gebrek aan gevoel of emosie, verlies van inhibisie,
- flouте, gevoelloosheid, sametrekking van 'n spier, bewussynsverlies, rukkerige bewegings, moeilik om te beweeg, duiseligheid wanneer jy opstaan, bewing tydens beweging, ongewone oogbewegings, verminderde bewussyn, probleme met dink, spraak versteuring, verminderde reflekse, verhoogde sensitiwiteit van die vel, brandende sensasie, verlies aan smaak, gevoel van liggaamlike ongemak, stuiptrekkings, verdraaiing van die reuksintuig, gedeeltelike of algehele verlies van spierbeweging, onvermoë om samehangend te skryf, as 'n simptoom van breinsiekte of skade,
- sig verlies, perifere sig verlies, visuele versteuring, oogswelling, gesigsvelddefek, verminderde visuele skerpte, oogpyn, oogtoestand wat homself manifesteer deur nie-spesifieke simptome soos moegheid, pyn in of om die oë, die teenwoordigheid van ligflitse, droë oë, waterige oë, oogirritasie,
- visuele veld versteuring, veranderde visuele diepte persepsie, abnormale verwyding van die pupil, skeelkyk van oog/oë, visuele helderheid,
- verhoogde sensitiwiteit vir klank,
- lae bloeddruk, hoë bloeddruk, warm gloede, rooiheid van die nek en gesig, voel koud,
- kort van asem, neusbloeding, hoes, verstopte neus, loopneus, snork, nasale droogheid, vog in die longe, toetrek van die keel,
- respiratoriese onderdrukking - stadige en vlak asemhaling,
- sooibrand, verhoogde speekselproduksie, gevoelloosheid rondom die mond, abdominale swelling, ontsteking van die pankreas, geswelde tong, probleme om te sluk,
- galbulte, oormatige sweet afskeiding, jeuk van die vel, koue sweet,
- swelling van gewrigte, pyn in 'n spier of spiere, spiertrekkings, nekpyn, spierstyfheid, afbreek van spierweefsel,
- probleme met seksuele funksionering insluitend onvermoë om 'n seksuele klimaks te bereik, verhoogde libido, probleme met ereksie, vertraagde ejakulasie, pynlike maandstondes, pyn in die borste, afwesigheid van maandstonde, borsafskeiding, vergrote borste, vergrote borste in mans,
- algemene swelling wat veroorsaak word deur vogretensie, swelling van die gesig, benoude bors, pyn, koors, dors, koue rillings, swakheid,
- veranderinge in bloed- en lewertoets resultate (verhoogde bloedkreatinienfosfokinase, verhoogde alanien amino transferase, verhoogde bloedglukose, verhoogde aspartaat amino transferase, verlaagde bloedplaatjietelling, verhoogde bloedkreatinien, verlaagde bloedkalium, verlaagde witbloedseltelling).

Frekwensie onbekend:
- gedagtes om jouself seer te maak of dood te maak.

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

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegkundige.
Jy kan ook newe-effekte aan SAHPRA rapporteer via 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 **GLOVIREG**.

5. Hoe om GLOVIREG te bewaar

Bewaar alle medisyne buite bereik van kinders.
- Bewaar by of benede 25 °C (kamertemperatuur). Beskerm teen lig.
- Stoor in die oorspronklike verpakking/houer.
- Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
- Moet nie in 'n badkamer bêre nie.
- Hou die houer dig toe.
- Moet nie na die vervaldatum wat aangebring is op die bottel/karton/etiket gebruik nie.

Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat GLOVIREG bevat
Die aktiewe bestanddeel is pregabalin.
Die ander bestanddele is:
Laktosemonohidraat, vooraf gelatiniseerde stysel en talk. Harde gelatienkapsule wat die volgende bevat,
GLOVIREG 25 bevat: gelatien, natriumlaurielsulfaat en titaniumdioksied.
GLOVIREG 75 bevat: gelatien, natriumlaurielsulfaat, titaniumdioksied en rooi ysteroksied.
GLOVIREG 150 bevat: gelatien, natriumlaurielsulfaat en titaniumdioksied.
Bevat suiker: laktosemonohidraat.
GLOVIREG 25 bevat 35 mg laktosemonohidraat per kapsule.
GLOVIREG 75 bevat 8,25 mg laktosemonohidraat per kapsule.
GLOVIREG 150 bevat 16,50 mg laktosemonohidraat per kapsule.

Hoe GLOVIREG lyk en inhoud van die pak
GLOVIREG 25: Wit/wit, grootte '4' harde gelatien kapsules wat witkleurige poeier bevat, met "M1" gedruk op die doppie en "25 mg" op die liggaam.

GLOVIREG 75: Bruin/wit grootte '4' harde gelatien kapsules wat witkleurige poeier bevat, met "M3" gedruk op die doppie en "75 mg" op die liggaam.

GLOVIREG 150: Wit/wit grootte '2' harde gelatien kapsules wat witkleurige poeier bevat, met "M5" gedruk op die doppie en "150 mg" op die liggaam.

Inhoud van die pak:
Stulpverpakking:
25 µ Aluminiumfoelie/ 6-8 gsm HSL as die dekmateriaal en deursigtige, PVC/PVdC film, 250 µ PVC/90 gsm PVdC as die vormingsmateriaal.
Verpakkingsgroottes sluit 14's, 56's, 60's of 100'e kapsules in.
HDPE-houer verpakking:
Ronde, wit HDPE houer met skroefnek, met wit kinderbestande sluiting met pulp en hitteseëlvoering.
Verpakkingsgrootte: 90 kapsules
* Nie alle verpakkingsgroottes word dalk bemark nie.

7. Houer van die Registrasiesertifikaat

MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid Afrika
Tel: +27 11 682 11 69

8. Hierdie inligtingstuk was hersien in

03 September 2024

9. Registrasienommers

GLOVIREG 25: 48/2.5/1109
GLOVIREG 150: 48/2.5/1110
GLOVIREG 75: 48/2.5/1111

Vir 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

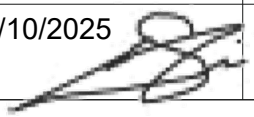
Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : According to SAHPRA's clinical approval for the clinical safety fluctuation and dimension change.

1. Product: GLOVIREG (Pregabalin Capsules)	
2. Country: South Africa (Private Market)	**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.: PM04340157**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40501 mini**
13. Barcode/NDC No: NA	**14. Supersedes Item code No: PM03838502**
15. Revision no: 02	**16. A/W File name: Z:\Pregabalin\SA Private market\02\GLOVIREG 25-75-150 mg PI & PIL - PM04340157.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
	03/10/2025 				

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.

Format No: FRM/SOP/CO/CQA/021/03-003

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM03838501	14/09/22	14/09/2022
2) Removal of English PI, inclusion of URL, change in dimension and date of revision.	PM03838502	02/07/24	16/06/2025
3) According to SAHPRA's clinical approval for the clinical safety fluctuation and dimension change.	PM04340157		