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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

VIGLYMAK 50 Tablets
Vildagliptin
Contains Sugar (Anhydrous Lactose 96 mg per tablet)

Read all of this leaflet carefully before you start taking VIGLYMAK 50
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.
VIGLYMAK 50 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 **VIGLYMAK 50** is and what it is used for
2. What you need to know before you take **VIGLYMAK 50**
3. How to take **VIGLYMAK 50**
4. Possible side effects
5. How to store **VIGLYMAK 50**
6. Contents of the pack and other information

1. What VIGLYMAK 50 is and what it is used for

VIGLYMAK 50 is a medicine used to treat patients with type 2 diabetes whose condition cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the blood. Such medicines are known as oral antidiabetics. **VIGLYMAK 50** works by making the pancreas produce insulin and less glucagon. **VIGLYMAK 50** helps to control your blood sugar level.
Your doctor will prescribe **VIGLYMAK 50** in combination with other antidiabetics depending on your condition. It is important that you continue to follow the diet and/or exercise advised for you, whilst you are on treatment with **VIGLYMAK 50**.
Ask your doctor if you have any questions about why **VIGLYMAK 50** has been prescribed for you.

2. What you need to know before you take VIGLYMAK 50

Do not take **VIGLYMAK 50**:
- If you are allergic (hypersensitive) to vildagliptin or any of the other ingredients of **VIGLYMAK 50**.
- If you have liver problems.

Warnings and precautions
Talk to your doctor before taking **VIGLYMAK 50**.
- if you have type 1 diabetes (i.e. your body does not produce insulin) or if you have a condition called diabetic ketoacidosis. **VIGLYMAK 50** should not be used in these conditions.
- if you are taking an anti-diabetic medicine known as a sulphonylurea (your doctor may want to reduce your dose of the sulphonylurea when you take it together with **VIGLYMAK 50** in order to avoid low blood glucose [hypoglycaemia]).
- if you have moderate or severe kidney disease your doctor may prescribe a lower dose of **VIGLYMAK 50**).
- If you are on dialysis
- If you have liver disease
- If you suffer from heart failure
- If you have or have had a disease of the pancreas

If you have previously taken vildagliptin but had to stop taking it because of liver disease, you should not take this medicine.
Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse. You are also advised to pay particular attention to new onset of blisters or ulcers while taking **VIGLYMAK 50**. Should these occur, you should promptly consult your doctor.
A test to determine your liver function will be performed before the start of **VIGLYMAK 50** treatment, at three month intervals for the first year and periodically thereafter. This is so that signs of increased liver enzymes can be detected as early as possible.
Your doctor will test your blood and urine for sugar regularly.

Children and adolescents
The use of **VIGLYMAK 50** in children and adolescents up to 18 years of age is not recommended.

Other medicines and VIGLYMAK 50
- 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 as the effect of **VIGLYMAK 50** may be reduced when taken together:
  - thiazides or other diuretics (also called water tablets)
  - corticosteroids (generally used to treat inflammation)
  - thyroid medicines
  - certain medicines affecting the nervous system.
  - Tell your doctor if you are taking ACE inhibitors (medicines used to treat high blood pressure), as there may be an increased risk of side effects when they are taken together with **VIGLYMAK 50**.

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 use **VIGLYMAK 50** during pregnancy. It is not known if **VIGLYMAK 50** passes into breast milk. You should not use **VIGLYMAK 50** if you are breast-feeding or plan to breast-feed.

Driving and using machines
If you feel dizzy while taking **VIGLYMAK 50**, do not drive or use any tools or machines.
It is not always possible to predict to what extent **VIGLYMAK 50** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **VIGLYMAK 50** affects you.

VIGLYMAK 50 contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

VIGLYMAK 50
PM04341121

VIGLYMAK 50 contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take VIGLYMAK 50

Do not share medicines prescribed for you with any other person.
Always take **VIGLYMAK 50** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
Your doctor will tell you exactly how many tablets of **VIGLYMAK 50** to take.
Your doctor will prescribe **VIGLYMAK 50** in combination with other antidiabetics if one medicine alone is not sufficient to control your blood sugar level
The usual dose is:
VIGLYMAK 50 once a day to be taken in the morning or **VIGLYMAK 50** twice a day to be taken in the morning and in the evening (50 mg twice a day).

Method of administration
The tablets should be swallowed whole with a glass of water.
Continue taking **VIGLYMAK 50** every day for as long as your doctor tells you. You may have to stay on the treatment for a long period of time. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.
If your doctor has told you to stop your treatment with **VIGLYMAK 50** because of liver problems you should never start taking **VIGLYMAK 50** again.
If you have questions about how long to take **VIGLYMAK 50**, talk to your doctor.
If you have the impression that the effect of **VIGLYMAK 50** is too strong or too weak, talk to your doctor or pharmacist.

If you take more VIGLYMAK 50 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. Medical attention may be necessary. If you have to go to a doctor or hospital, take the pack and this leaflet with you.

If you forget to take VIGLYMAK 50
If you forget to take a dose of this medicine, take it as soon as you remember. Then take your next dose at the usual time. If it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten tablet.

If you stop taking VIGLYMAK 50
Continue to take this medicine as long as your doctor prescribes it so that it can continue to control your blood sugar. Do not stop taking **VIGLYMAK 50** unless your doctor tells you to. If you have any questions about how long to take this medicine, talk to your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

VIGLYMAK 50 can have side effects.
Not all side effects reported for **VIGLYMAK 50** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **VIGLYMAK 50**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **VIGLYMAK 50** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to **VIGLYMAK 50**. 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:
- Swelling of the pancreas – you may experience pain in the abdomen, nausea, vomiting, fever and chills, shortness of breath and fast heartbeat.
- Swelling of the liver you may experience pain in the abdomen, nausea, vomiting, fatigue, yellowing of the skin and whites of the eyes

These are all very serious side effects. If you have them, you may have had a serious reaction to **VIGLYMAK 50** You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
Frequent side effects:
- nausea (feeling sick), vomitting
- abdominal cramps or stomach pains,
- headache,
- dizziness,
- tiredness,
- low blood sugar – you may experience shaking, sweating, anxiety, dizziness or hunger,
- acid reflux – you may experience a burning sensation in your chest, backwash of food in the throat, upper belly pain, chest pain, trouble swallowing.
- tremor
- abnormally excessive sweating
- weakness, chills
- swelling of the body, hands and feet
- blurred vision
- increase in weight
- itchy, dry skin or scaly rash

Less frequent side effects:
- runny nose, sneezing, congestion
- muscle cramps,
- flatulence or wind,
- diarrhoea,
- loss of appetite
- tiredness
- constipation
- joint pain

- 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 **VIGLYMAK 50**, 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com. By reporting side effects, you can help provide more information on the safety of **VIGLYMAK 50.**

5. How to store VIGLYMAK 50

Store at or below 30 °C.
KEEP OUT OF THE REACH OF CHILDREN.
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 VIGLYMAK 50 contains
The active ingredient is Vildagliptin
Contains sugar – anhydrous lactose
The other ingredients are:
Anhydrous Lactose / Lactose
Microcrystalline Cellulose
Sodium Starch Glycolate Type A (Glycolys)
Magnesium stearate

What VIGLYMAK 50 looks like and contents of the pack
VIGLYMAK 50: White to off white, round, flat faced beveled edge, uncoated tablets debossed with "L45" on one side and plain on other side.
VIGLYMAK 50: Each tablet contains Vildagliptin 50 mg.

Contents of the pack:
Blister Pack:
Tablets are packed in Cold Form Laminate: 25 µ OPA/ 45 µ Aluminium foil/60 µ PVC as the forming material and plain 25 µ aluminium foil with 6-8 gsm heat seal lacquer as the lidding material, packed in pre-printed carton.
Pack size include 10's, 28's, 30's, 56's and 60's tablets.
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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02 September 2025

Registration numbers
VIGLYMAK 50: 57/21.2/0584

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

335 mm

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PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S3

VIGLYMAK 50 Tablette
Vildagliptien
Bevat suiker (Anhidiriese laktose 96 mg per tablet)

Lees hierdie hele inligtingstuk noukeurig deur voordat jy VIGLYMAK 50 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.
- **VIGLYMAK 50** 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 **VIGLYMAK 50** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **VIGLYMAK 50** neem
3. Hoe om **VIGLYMAK 50** te neem
4. Moontlike newe-effekte
5. Hoe om **VIGLYMAK 50** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat VIGLYMAK 50 is en waarvoor dit gebruik word

VIGLYMAK 50 is 'n medisyne wat gebruik word om pasiënte met tipe 2 diabetes te behandel wie se toestand nie deur dieet en oefening alleen beheer kan word nie. Dit help om die vlak van suiker in die bloed te beheer. Sulke medisyne staan bekend as orale anti-diabetika. **VIGLYMAK 50** werk deur die pankreas te laat insulien produseer, en minder glukagon. **VIGLYMAK 50** help om jou bloedsuikervlak te beheer.
Jou dokter sal **VIGLYMAK 50** voorskryf in kombinasie met ander anti-diabetika, afhangende van jou toestand. Dit is belangrik dat jy, terwyl jy op behandeling met **VIGLYMAK 50** is, aanhou om die dieet en/of oefening te volg wat vir jou aanbeveel is.
Vra jou dokter as jy enige vrae het oor hoekom **VIGLYMAK 50** vir jou voorgeskryf is.

2. Wat jy behoort te weet voordat jy VIGLYMAK 50 neem

Moet nie VIGLYMAK 50 neem nie:
- Indien jy allergies (hipersensitief) is vir vildagliptien of enige van die ander bestanddele van **VIGLYMAK 50**, gelys in **afdeling 6**.
- Indien jy lewerprobleme het.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter voordat jy **VIGLYMAK 50** neem:
- indien jy tipe 1 diabetes het (dit wil sê jou liggaam produseer nie insulien nie) of as jy 'n toestand het wat diabetiese keto-asidosis genoem word. **VIGLYMAK 50** moet nie in hierdie toestande gebruik word.
- indien jy 'n anti-diabetiese medisyne neem wat bekend staan as 'n sulfonielureum (jou dokter mag dalk jou dosis van die sulfonielureum wil verminder wanneer jy dit saam met **VIGLYMAK 50** neem om sodoende lae bloedglukose [hipoglukemie] te voorkom)
- indien jy matige of ernstige niersiekte het (jou dokter mag 'n laer dosis van **VIGLYMAK 50** voorskryf)
- indien jy op dialise is
- indien jy lewersiekte het
- indien jy aan hartversaking ly
- indien jy 'n siekte van die pankeas het of gehad het

Indien jy voorheen vildagliptien geneem het, maar moes ophou om dit te neem as gevolg van lewersiekte, moet jy nie hierdie medisyne neem nie.
Diabetiese velletsels is 'n algemene komplikasie van diabetes. Jy word aangeraai om die aanbevelings vir vel- en voetversorging wat jy van jou dokter of verpleegkundige ontvang, te volg. Jy word ook aangeraai om besondere aandag te gee aan die nuwe vorming van blase of ulkusse terwyl jy **VIGLYMAK 50** neem. Sou hierdie voorkom, moet jy dadelik jou dokter raadpleeg.
'n Toets om jou lewerfunksie te bepaal, sal voor die aanvang van **VIGLYMAK 50** behandeling gedoen word, met 'n interval van drie maande vir die eerste jaar en periodiek daarna. Dit is sodat tekens van verhoogde lewerensieme so vroeg as moontlik opgemerk kan word.
Jou dokter sal jou bloed en uriene gereeld vir suiker toets.

Kinders en adolessente
Die gebruik van **VIGLYMAK 50** in kinders en adolessente tot op 18 jarige ouderdom word nie aanbeveel.

Ander medisyne en VIGLYMAK 50 mg
Vertel altyd 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, aangesien die effek van **VIGLYMAK 50** verminder kan word wanneer dit saam geneem word:
- tiasiede of ander diuretika (ook genoem watertablette)
- kortikosteroïede (algemeen gebruik om inflammasie te behandel)
- tiroïed medisyne
- sekere medisyne wat die senuweestelsel affekteer
- Vertel jou dokter indien jy AOE-inhibeerders neem (middels wat gebruik word om hoë bloeddruk te behandel), aangesien daar 'n verhoogde risiko van newe-effekte kan wees wanneer dit saam met **VIGLYMAK 50** geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, dink dat jy dalk swanger is of beplan om 'n baba te hê, vra jou dokter of apteker vir advies voordat hierdie medisyne geneem word.
Jy moet nie **VIGLYMAK 50** tydens swangerskap gebruik nie. Dit is nie bekend of **VIGLYMAK 50** in borsmelk oorgaan nie. Jy moet nie **VIGLYMAK 50** gebruik indien jy borsvoed of beplan om te borsvoed nie.

Bestuur en gebruik van masjinerie
Indien jy duiselig voel terwyl jy **VIGLYMAK 50** neem, moet jy nie bestuur of enige gereedskap of masjiene gebruik nie.
Dit is nie altyd moontlik om te voorspel tot watter mate **VIGLYMAK 50** met jou daaglikse aktiwiteite kan inmeng nie. Jy moet seker maak dat jy nie in die bogenoemde aktiwiteite betrokke raak nie, totdat jy bewus is van die mate waartoe **VIGLYMAK 50** jou affekteer.

VIGLYMAK 50 bevat laktose
Indien jou dokter jou vertel het dat jy 'n onverdraagsaamheid vir sommige suikers het, kontak jou dokter voordat jy hierdie medisyne neem.

VIGLYMAK 50 bevat natrium
Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per tablet, dit is dus essensieël 'natrium-vry'.

3. Hoe om VIGLYMAK 50 te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **VIGLYMAK 50** presies soos wat jou dokter jou aangesê het.
Jy moet met jou dokter of apteker bevestig indien jy nie seker is nie.
Jou dokter sal jou presies sê hoeveel tablette van **VIGLYMAK 50** jy moet neem.
Jou dokter sal **VIGLYMAK 50** voorskryf in kombinasie met ander anti-diabetika indien een middel alleen nie voldoende is om jou bloedsuikervlak te beheer nie.
Die gewone dosis is:
VIGLYMAK 50 een keer per dag om soggens geneem te word, of **VIGLYMAK 50** twee keer per dag om soggens en saans geneem te word (50 mg twee keer per dag).

Metode van toediening
Die tablette moet heel ingesluk word met 'n glas water.
Hou aan om **VIGLYMAK 50** elke dag te neem vir so lank as wat jou dokter jou aansê. Jy mag dalk vir 'n lang tydperk op die behandeling moet bly. Jou dokter sal jou toestand gereeld monitor om te kontroleer of die behandeling die gewenste effek het.
Indien jou dokter vir jou gesê het om jou behandeling met **VIGLYMAK 50** te stop weens lewerprobleme, moet jy nooit weer **VIGLYMAK 50** begin neem nie.
Indien jy vrae het oor hoe lank om **VIGLYMAK 50** te neem, praat met jou dokter.
Indien jy die onder die indruk is dat die effek van **VIGLYMAK 50** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer VIGLYMAK 50 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. Mediese hulp kan nodig wees. As jy na 'n dokter of hospitaal moet gaan, neem die pakkie en hierdie inligtingstuk saam met jou.

Indien jy vergeet om VIGLYMAK 50 te neem
Indien jy vergeet om 'n dosis van hierdie medisyne te neem, neem dit so gou as wat jy daarvan onthou. Neem dan jou volgende dosis op die gewone tyd. As dit amper tyd is vir jou volgende dosis, slaan die dosis wat jy gemis het oor. Moet nie 'n dubbele dosis neem, om op te maak vir 'n vergete tablet nie.

Indien jy ophou om VIGLYMAK 50 te neem
Gaan voort om hierdie medisyne te neem vir solank as wat jou dokter dit voorskryf sodat dit jou bloedsuiker kan aanhou beheer. Moet nie ophou om **VIGLYMAK 50** te neem nie, tensy jou dokter jou aansê om dit te doen. Indien jy enige vrae het oor hoe lank om hierdie medisyne te neem, praat met jou dokter. As jy enige verdere vrae het oor die gebruik van hierdie medisyne, vra jou dokter of apteker.

4. Moontlike newe-effekte

VIGLYMAK 50 kan newe-effekte hê.
Nie alle newe-effekte wat vir **VIGLYMAK 50** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verswak of indien jy enige ongunstige effekte ervaar terwyl jy **VIGLYMAK 50** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om **VIGLYMAK 50** te neem en kontak onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel wat probleme kan veroorsaak om te sluk of om asem te haal.
- uitslag of gejeuk,
- floute

Hierdie is alles baie ernstige newe-effekte. Indien jy dit kry, het jy moontlik 'n ernstige reaksie op **VIGLYMAK 50** gehad. Jy benodig moontlik dringende mediese aandag of hospitalisering.
Vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
- Swelling van die pankreas – jy mag pyn in die buik ervaar, naarheid, braking, koors en koue rillings, kortasem en 'n vinnige hartklop.
- Swelling van die lewer – jy mag pyn in die buik ervaar, naarheid, braking, moegheid, geel verkleuring van die vel en wit van die oë.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige reaksie op **VIGLYMAK 50** gehad het. Jy mag dringend mediese aandag of hospitalisering benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereelde newe-effekte:
- naarheid (siek gevoel), braking,
- abdominale krampe of maagpyn,
- hoofpyn,
- duiseligheid,
- moegheid,
- lae bloedsuiker – jy kan bewerasies, sweet, angs, duiseligheid of honger ervaar,
- suurrefluks - jy kan 'n branderige gevoel in jou borskas ervaar, terugvloei van kos in die keel, boonste buikpyn, borskaspyn, probleme met sluk,
- bewing,
- abnormale oormatige sweet,
- swakheid, koue rillings,
- swelling van die ligaam, hande en voete,
- dowwe visie,
- gewigstoename,
- jeukerige, droë vel of skubberige uitslag

Minder gereelde newe-effekte:
- loopneus, nies, kongestie,
- spierkrampe,
- winderigheid of winde,
- diarree,
- verlies van eetlus,
- moegheid,
- hardlywigheid,
- gewrigspyn

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 versleg of indien jy enige ongewenste effekte ervaar terwyl **VIGLYMAK 50** geneem word, 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 is nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA se webwerf gevind word, of aan Macleods Pharmaceuticals SA (Edms) Bpk. by safety@macleodspharma.com. Deur newe-effekte aan te meld kan jy help om meer inligting te verskaf aangaande die veiligheid van **VIGLYMAK 50.**

5. Hoe om VIGLYMAK 50 mg te bewaar

Bewaar by of benede 30 °C.
BEWAAR BUITE DIE BEREIK VAN KINDERS.
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 stulp / 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 die pak en ander inligting

Wat VIGLYMAK 50 bevat
Die aktiewe bestanddeel is 50 mg vildagliptien
Bevat suiker – anhidriese laktose
Die ander bestanddele is:
Anhidriese laktose / laktose
Mikrokristallyne sellulose
Natriumstyselglikolaat Tipe A (Glikolis)
Magnesiumstearaat

Hoe VIGLYMAK 50 mg lyk en inhoud van die pak
VIGLYMAK 50: Wit tot af-wit, ronde, plat gesig met afgekapte rand, onbedekte tablette bedruk met "L45" aan die een kant en glad aan die ander kant.
VIGLYMAK 50: Elke tablet bevat 50 mg Vildagliptien.

Inhoud van die pak:
Stulpstrook verpakking:
Tablette word verpak in Koue Vorm Laminaat: 25 µ OPA/ 45 µ Aluminiumfoelie/ 60 µ PVC as die vormingsmateriaal en gewone 25 µ aluminiumfoelie met 6-8 gsm hitte-seëllak as die dekmateriaal, verpak in 'n voorafgedrukte karton.
Verpakkingsgroottes sluit 10's, 28's, 30's, 56's, 60's tablette in.
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),
1 Cussonia-rylaan,
Bassonia Rock, Uitbr. 12
Alberton
Gauteng

Hierdie inligtingstuk was laas hersien in

Registrasienommers
VIGLYMAK 50: 57/21.2/0584

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

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: VIGLYMAK 50 (Vildagliptin Tablet 50 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 300 (W) mm**
9. Design / Style: Booklet type	**10. Item code No.: PM04341121**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40804 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: NA**
15. Revision no: 00	**16. A/W File name:E:\SOUTH AFRICA\South Africa\Vildagliptin Tablets\Vildagliptin Tablets 50 mg PIL - PM04341121.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	08/01/2025				

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/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa - Private Market	**PM04341121**		