Front Top

350 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

VIGLYMAK PLUS 50/850 mg tablets
Contains 50 mg Vildagliptin and 850 mg Metformin hydrochloride.
Sugarfree.
VIGLYMAK PLUS 50/1 000 mg tablets
Contains 50 mg Vildagliptin and 1 000 mg Metformin hydrochloride.
Sugarfree

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

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

VIGLYMAK PLUS is a medicine used to treat type 2 diabetes. It contains 2 active substances, Vildagliptin and Metformin hydrochloride. **VIGLYMAK PLUS** helps to control the level of sugar in the blood. Such medicines are known as oral antidiabetics.
Your doctor has prescribed **VIGLYMAK PLUS** for you if your blood sugar level has been controlled when you take vildagliptin and metformin hydrochloride as separate tablets and at the same dosages.
VIGLYMAK PLUS can also be prescribed for you in combination with a sulphonylurea if your blood sugar level has been controlled on vildagliptin, metformin hydrochloride and a sulphonylurea as separate tablets and the same dosages. **VIGLYMAK PLUS** can also be prescribed for you as add-on to insulin if your blood sugar levels have been controlled on a stable dose of insulin plus vildagliptin and metformin hydrochloride as separate tablets and the same dosages. It is important that you continue to follow the diet and/or exercise advised for you whilst you are on treatment with **VIGLYMAK PLUS**.
Ask your doctor if you have any questions about why **VIGLYMAK PLUS** has been prescribed for you.

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

Do not take VIGLYMAK PLUS:
- if you are allergic to vildagliptin, metformin hydrochloride or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic to any of these, talk to your doctor before taking **VIGLYMAK PLUS**.
- if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see "Risk of lactic acidosis" below) or ketoacidosis. Ketoacidosis is a condition in which substances called ketone bodies accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- if you have recently had a heart attack or if you have heart failure or serious problems with your blood circulation or difficulties in breathing.
- if you have severely reduced kidney function.
- if you have liver problems.

VIGLYMAK PLUS
50/850, 50/1 000
PM04342876

Warnings and precautions
Take special care with **VIGLYMAK PLUS**
VIGLYMAK PLUS is not a substitute for insulin. Therefore, you should not receive VIGLYMAK PLUS for the treatment of type 1 diabetes or for the treatment of a condition called diabetic ketoacidosis.
Risk of lactic acidosis
VIGLYMAK PLUS may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. Stop taking **VIGLYMAK PLUS** and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma. Symptoms of lactic acidosis include: - vomiting - stomach ache (abdominal pain) - muscle cramps - a general feeling of not being well with severe tiredness - difficulty in breathing - reduced body temperature and heartbeat. Lactic acidosis is a medical emergency and must be treated in a hospital.
If you are going to have a contrast x-ray (a specific type of x-ray involving an injectable dye). You will need to temporarily stop taking **VIGLYMAK PLUS** at the time of and for a few days after the procedure.
Talk to your doctor, pharmacist or nurse before taking **VIGLYMAK PLUS** 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 PLUS** in order to avoid low blood glucose (hypoglycaemia).
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 PLUS**. Should these occur, you should promptly consult your doctor.
VIGLYMAK PLUS may cause a condition known as severe cutaneous adverse reactions (SCARS). These are a group of potentially lethal adverse drug reactions that involve the skin and mucous membranes of various body openings such as the eyes, ears, and inside the nose, mouth, and lips. In more severe cases, SCARs also involve serious damage to internal organs. It is characterised by fever and flu-like symptoms followed by mucous membrane blisters i.e. inside the nose, mouth, lips.
If you need to have major surgery, you must stop taking **VIGLYMAK PLUS** during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with **VIGLYMAK PLUS**.
A test to determine your liver function will be performed before the start of **VIGLYMAK PLUS** 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.
During treatment with **VIGLYMAK PLUS**, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or have worsening renal function.
Your doctor will test your blood and urine for sugar regularly.
VIGLYMAK PLUS can cause a rare muscle injury that caused a breakdown of muscle. This presents as intense muscle aching or swelling, dark red or brown urine or little to no urine.
VIGLYMAK PLUS can cause a decrease in your Vitamin B_{12} levels. Your doctor will do regular blood tests for Vitamin B_{12}.

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

Other medicines and VIGLYMAK PLUS
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 they may cause increased side effects, they may affect how **VIGLYMAK PLUS** works or how **VIGLYMAK PLUS** might affect other medicines work:
- glucocorticoids generally used to treat inflammation such as prednisone, cortisone and dexamethasone
- beta-2 agonists generally used to treat respiratory disorders, such as salbutamol and albuterol
- other medicines used to treat diabetes such as glyburide.
- medicines which increase urine production (diuretics) like furosemide.
- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
- certain medicines for the treatment of high blood pressure (called ACE inhibitors and angiotensin II receptor antagonists), such as captopril, enalapril and lisinopril
- certain medicines affecting the thyroid such as levothyroxine
- certain medicines affecting the nervous system such as fluphenazine, trifluoperazine, chlorpromazine
- certain medicines used to treat angina (e.g. ranolazine)
- certain medicines used to treat HIV infection (e.g. dolutegravir)
- certain medicines used to treat a specific type of thyroid cancer (medullary thyroid cancer) (e.g. vandetanib)
- certain medicines used to treat heart burn and peptic ulcers (e.g cimetidine).

VIGLYMAK PLUS with food and drink and alcohol:
Avoid excessive alcohol intake while taking **VIGLYMAK PLUS** since this may increase the risk of lactic acidosis (please see section "Warnings and precautions").

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **VIGLYMAK PLUS**.
Do not take **VIGLYMAK PLUS** if you are pregnant.
Do not breastfeed if you are taking **VIGLYMAK PLUS**.
If you are a woman of childbearing age, make sure you use effective contraception while on treatment with **VIGLYMAK PLUS**.

Driving and using machines
If you feel dizzy while taking **VIGLYMAK PLUS**, do not drive or use any tools or machines.
It is not always possible to predict to what extent **VIGLYMAK PLUS** 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 PLUS** affects you.

3. How to take VIGLYMAK PLUS

Do not share medicines prescribed for you with any other person.
Always take **VIGLYMAK PLUS** 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 how long your treatment with **VIGLYMAK PLUS** will last. Do not stop treatment early because this may affect the control of your blood sugar levels. If you have the impression that the effect of **VIGLYMAK PLUS** is too strong or too weak, tell your doctor or pharmacist.

The usual dose is one tablet of either **VIGLYMAK PLUS** 50 mg/850 mg or **VIGLYMAK PLUS** 50 mg/1 000 mg twice a day:
Your doctor will tell you which strength and exactly how many tablets of **VIGLYMAK PLUS** to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose. Do not take more **VIGLYMAK PLUS** than your doctor has prescribed.
Method of administration
VIGLYMAK PLUS should be taken in the morning and/or evening. It is recommended that you take your tablets either with or just after food. This will reduce the chance of you getting an upset stomach.
The tablets should be swallowed whole with a glass of water.
Continue taking **VIGLYMAK PLUS** every day for as long as your doctor tells you. You may have to stay on this 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 tells you to stop your treatment with **VIGLYMAK PLUS** because of liver problems, you should never start taking **VIGLYMAK PLUS** again.
If you have questions about how long to take **VIGLYMAK PLUS**, talk to your doctor.

If you take more VIGLYMAK PLUS 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 PLUS
If you forget to take a tablet, take it with your next meal unless you are due to take one then anyway. Do not take a double dose (two tablets at once) to make up for a forgotten tablet.

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

If any of the following happens, stop taking **VIGLYMAK PLUS** 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 PLUS**. 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:
- lactic acidosis where symptoms of feeling cold and uncomfortable, muscle pain, drowsiness, severe nausea or vomiting, abdominal pain, unexplained weight loss, dizziness, irregular heartbeat, or rapid breathing are experienced
- weak muscles, muscle stiffness, muscle pain and a change in your urine colour
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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

Tell your doctor if you notice any of the following:
Frequent side effects:
- nausea (feeling sick),
- abdominal cramps or stomach pains,
- headache,
- dizziness,
- tiredness,
- light-headedness,
- low blood sugar, you may have confusion, hunger, nausea, anxiety, shakiness, headache, feel weak
- chills
- acid reflux
- tremor
- abnormally excessive sweating
- weakness
- metallic taste
- diarrhoea
- loss of appetite

Less frequent side effects:
- dry cough,
- muscle cramps,
- flatulence or wind, constipation
- diarrhoea,
- nose, throat and chest infection
- swelling of the leg
- decrease in the level of vitamin B12 in the blood (determined by blood tests)
- liver problems and abnormal liver function test results
- rash, itching and redness of the skin

Frequency unknown
- Swelling of the pancreas which may cause severe abdominal swelling, bloating, loss of appetite and fever.
- Muscle pain
- Formation of blisters on the skin

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 PLUS**, 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 PLUS.**

5. How to store VIGLYMAK PLUS

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 dates dated 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 PLUS contains
VIGLYMAK PLUS 50/850
The active ingredients are 50 mg vildagliptin and 850 mg metformin hydrochloride.
VIGLYMAK PLUS 50/1000
The active ingredients are 50 mg vildagliptin and 1 000 mg metformin hydrochloride.
Sugar free
The other ingredients are:
Hydroxypropyl Cellulose HPC-L
Microcrystalline Cellulose Avicel PH 101
Isopropyl alcohol
Magnesium stearate
Film coating containing:
HPMC 2910/Hypromellose 6 mPas
Titanium Dioxide
Macrogol/PEG
Iron oxide yellow
Talc

What VIGLYMAK PLUS looks like and contents of the pack
VIGLYMAK PLUS 50/850: Each film-coated tablet - Yellow colored, oval shaped, biconvex, film-coated tablet, debossed with "F59" on one side and plain on other side.
VIGLYMAK PLUS 50/1 000: Each film-coated tablet - Dark yellow colored, oval shaped, biconvex, film- coated tablet, debossed with "F60" on one side and plain on other side.

Contents of the pack:
Blister pack :
Tablets are packed in a blister containing plain aluminium foil with heat seal lacquered as the lidding material and clear PVC/PVDC as the forming material. The blister is packed in an outer carton.
Blister pack cold form:
Tablets are packed in a blister containing plain aluminium foil with heat seal lacquered as the lidding material and cold form laminate as the forming material. The blister is packed in an outer carton.

Pack size include 30's,60's,120's,180's and 360'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

This leaflet was last revised in
25 June 2025

Registration numbers
VIGLYMAK PLUS 50/850: 57/21.2/0368.366
VIGLYMAK PLUS 50/1 000: 57/21.2/0369.367

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

Back Top

350 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S3

VIGLYMAK PLUS 50/850 mg tablette
Bevat 50 mg vildagliptien en 850 mg metformienhidrochloried.
Suikervry.
VIGLYMAK PLUS 50/1 000 mg tablette
Bevat 50 mg vildagliptien en 1 000 mg metformienhidrochloried.
Suikervry

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

1. Wat VIGLYMAK PLUS is en waarvoor dit gebruik word

VIGLYMAK PLUS is 'n medisyne wat gebruik word om tipe 2-diabetes te behandel. Dit bevat 2 aktiewe stowwe, vildagliptien en metformienhidrochloried. **VIGLYMAK PLUS** help om die vlak van suiker in die bloed te beheer. Sulke medisyne staan bekend as orale antidiabetika.
Jou dokter het **VIGLYMAK PLUS** vir jou voorgeskryf indien jou bloedsuikervlak beheer is wanneer jy vildagliptien en metformienhidrochloried as aparte tablette en in dieselfde dosisse neem. **VIGLYMAK PLUS** kan ook vir jou voorgeskryf word in kombinasie met 'n sulfonielureum as jou bloedsuikervlak beheer is op vildagliptien, metformienhidrochloried en 'n sulfonielureum as aparte tablette en dieselfde dosisse. **VIGLYMAK PLUS** kan ook vir jou as byvoeging tot insulien voorgeskryf word indien jou bloedsuikervlakke beheer is met 'n stabiele dosis van insulien plus vildagliptien en metformienhidrochloried as aparte tablette en dieselfde dosisse. Dit is belangrik dat jy voortgaan om die dieet en/of oefening te volg wat vir jou voorgestel word terwyl jy op behandeling met **VIGLYMAK PLUS** is.
Vra jou dokter indien jy enige vrae het oor hoekom **VIGLYMAK PLUS** vir jou voorgeskryf is.

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

Moet nie VIGLYMAK PLUS neem nie:
- indien jy allergies is vir vildagliptien, metformienhidrochloried of enige van die ander bestanddele van hierdie medisyne (gelys in afdeling 6). As jy dink jy kan allergies wees vir enige van hierdie, praat met jou dokter voordat jy **VIGLYMAK PLUS** neem.
- indien jy onbeheerde diabetes het, met byvoorbeeld ernstige hiperglukemie (hoë bloedglukose), naarheid, braking, diarree, vinnige gewigsverlies, melksuur asidose (sien "Risiko van melksuur asidose" hieronder) of ketoasidose. Ketoasidose is 'n toestand waarin stowwe wat ketoonliggame genoem word, ophoop in die bloed en wat kan lei tot diabetiese pre-koma. Simptome sluit in maagpyn, vinnig en diep asemhaling, slaperigheid of jou asem wat 'n ongewone vrugte reuk ontwikkel.
- indien jy onlangs 'n hartaanval gehad het of as jy hartversaking of ernstige probleme met jou bloedsomloop het of probleme met asemhaling.
- indien jy ernstig verminderde nierfunksie het.
- indien jy lewerprobleme het.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **VIGLYMAK PLUS**:
VIGLYMAK PLUS is nie 'n plaasvervanger vir insulien nie. Daarom moet jy nie VIGLYMAK PLUS ontvang vir die behandeling van tipe 1-diabetes of vir die behandeling van 'n toestand naamlik diabetiese ketoasidose nie.
Risiko van melksuur asidose
VIGLYMAK PLUS kan 'n baie seldsame, maar baie ernstige newe-effek naamlik melksuur asidose veroorsaak, veral as jou niere nie behoorlik werk nie. Hou op om **VIGLYMAK PLUS** te neem en kontak 'n dokter of die naaste hospitaal onmiddellik indien jy van die simptome van melksuur asidose ervaar, aangesien hierdie toestand tot koma kan lei. Simptome van melksuur asidose sluit in: - braking - maagpyn (abdominale pyn) - spierkrampe - 'n algemene gevoel van nie goed voel nie met ernstige moegheid - moeilike asemhaling - verlaagde liggaamstemperatuur en hartklop. Melksuur asidose is 'n mediese noodgeval en moet in 'n hospitaal behandel word.
Indien jy 'n kontras x-straal gaan hê ('n spesifieke tipe x-straal wat 'n inspuitbare kleurstof behels). Jy sal tydelik moet ophou om **VIGLYMAK PLUS** te neem tydens, en vir 'n paar dae na, die prosedure.
Praat met jou dokter, apteker of verpleegkundige voordat jy **VIGLYMAK PLUS** neem indien jy 'n anti-diabetiese medisyne bekend as 'n sulfonielureum neem. Jou dokter sal moontlik jou dosis van die sulfonielureum wil verminder wanneer jy dit saam met **VIGLYMAK PLUS** neem om sodoende lae bloed glukose (hipoglukemie) te vermy.
As jy voorheen vildagliptien geneem het, maar moes ophou weens 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 deur jou dokter of verpleegkundige gegee word, te volg. Jy word ook aangeraai om veral aandag te skenk aan die aanvang van nuwe blase of ulkusse terwyl **VIGLYMAK PLUS** geneem word. Indien dit voorkom, moet jy onmiddellik jou dokter raadpleeg.
VIGLYMAK PLUS kan 'n toestand veroorsaak wat bekend staan as ernstige kutaneuse nadelige reaksies (SCARS). Dit is 'n groep potensieel dodelike nadelige geneesmiddelreaksies wat die vel en slymvliese van verskeie liggaamsopeninge soos die oë, ore, en binne-in die neus, mond, en lippe aantas. In meer ernstige gevalle behels SCARs ook ernstige skade aan interne organe. Dit word gekenmerk deur koors en griepagtige simptome gevolg deur slymvliesblase, d.w.s. binne-in die neus, mond, lippe.
Indien jy 'n groot operasie moet ondergaan, moet jy ophou om **VIGLYMAK PLUS** gedurende en vir 'n geruime tyd na die prosedure te neem. Jou dokter sal besluit wanneer jy moet stop en wanneer jy weer jou behandeling met **VIGLYMAK PLUS** moet begin.
'n Toets om jou lewerfunksie te bepaal sal uitgevoer word voor die aanvang van behandeling met **VIGLYMAK PLUS**, met tussenposes van drie maande vir die eerste jaar en periodiek daarna. Dit is sodat tekens van verhoogde lewerensieme so vroeg as moontlik opgespoor kan word.
Tydens behandeling met **VIGLYMAK PLUS**, sal jou dokter jou nierfunksie ten minste een keer 'n jaar nagaan, of meer gereeld indien jy bejaard is, en/of verslegtende nierfunksie het.
Jou dokter sal jou bloed en uriene gereeld vir suiker toets.
VIGLYMAK PLUS kan 'n seldsame spierbesering veroorsaak wat 'n afbraak van spiere tot gevolg het. Dit presenteer as intense spierpyn of swelling, donkerrooi of bruin uriene of min tot geen uriene.
VIGLYMAK PLUS kan 'n afname in jou vitamien B_{12}-vlakke veroorsaak. Jou dokter sal gereeld bloedtoetse doen vir vitamien B_{12}.

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

Ander medisyne en VIGLYMAK PLUS
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel jou dokter of apteker indien jy enige van die volgende medisyne gebruik, aangesien dit verhoogde newe-effekte kan veroorsaak, dit kan beïnvloed hoe **VIGLYMAK PLUS** werk of hoe **VIGLYMAK PLUS** ander medisyne se werk kan beïnvloed:
- glukokortikoïede wat algemeen gebruik word om inflammasie te behandel, soos prednisoon, kortisoon en deksametasoon
- beta-2 agoniste wat algemeen gebruik word vir die behandeling van respiratoriese afwykings, soos salbutamol en albuterol
- ander medisyne wat gebruik word om diabetes te behandel, soos gliburied
- medisyne wat urienproduksie verhoog (diuretika) soos furosemied
- medisyne wat gebruik word om pyn en inflammasie te behandel (NSAIM en COX-2 inhibeerders, soos ibuprofen en selekoksib)
- sekere medisyne vir die behandeling van hoë bloeddruk (naamlik AOE inhibeerders en angiotensien II reseptor antagoniste) soos kaptopril, enalapril en lisinopril
- sekere medisyne wat die tiroïed beïnvloed, soos levotiroksien
- sekere medisyne wat die senuweestelsel aantas soos flufenasien, trifluoperasien, chloorpromasien
- sekere medisyne wat gebruik word om angina te behandel (bv. ranolasien)
- sekere medisyne wat gebruik word om MIV infeksie te behandel (bv. dolutegravir)
- sekere medisyne wat gebruik word om 'n spesifieke tipe skildklierkanker (medullêre tiroïedkanker) te behandel (bv. vandetanib)
- sekere medisyne wat gebruik word om sooibrand en maagsere te behandel (bv. simetidien).

VIGLYMAK PLUS met voedsel, vloeistof en alkohol:
Vermy oormatige alkohol inname terwyl **VIGLYMAK PLUS** geneem word, aangesien dit die risiko van melksuur asidose kan verhoog (sien asseblief afdeling "Waarskuwings en voorsorgmaatreëls").

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is, of jou baba borsvoed, vermoed dat jy moontlik swanger is, of beplan om 'n baba te kry, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **VIGLYMAK PLUS** neem.
Moet nie **VIGLYMAK PLUS** neem indien jy swanger is nie.
Moet nie borsvoed indien jy **VIGLYMAK PLUS** neem nie.
Indien jy 'n vrou van kinderbarende ouderdom is, maak seker dat jy effektiewe voorbehoedmiddel gebruik tydens behandeling met **VIGLYMAK PLUS**.

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

3. Hoe om VIGLYMAK PLUS te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **VIGLYMAK PLUS** presies soos wat jou dokter jou opdrag gegee het. Jy moet met jou dokter of apteker bevestig indien jy nie seker is nie.
Jou dokter sal vir jou sê hoe lank jou behandeling met **VIGLYMAK PLUS** sal duur. Moet nie vroeër met behandeling ophou nie,omdat dit die beheer van jou bloedsuikervlakke kan beïnvloed. Indien jy die indruk kry dat die effek van **VIGLYMAK PLUS** te sterk of te swak is, vertel jou dokter of apteker.

Die gewone dosis is een tablet van óf **VIGLYMAK PLUS** 50 mg/850 mg óf **VIGLYMAK PLUS** 50 mg/1 000 mg twee keer per dag:
Jou dokter sal jou vertel watter sterkte en presies hoeveel tablette van **VIGLYMAK PLUS** om te neem.
Afhangende van hoe jy op die behandeling reageer, kan jou dokter 'n hoër of laer dosis voorstel. Moet nie meer **VIGLYMAK PLUS** neem as wat jou dokter voorgeskryf het nie.
Metode van toediening
- **VIGLYMAK PLUS** moet in die oggend en/of aand geneem word. Dit word aanbeveel dat jy jou tablette of met of net na kos neem. Dit sal die kans verminder dat jy 'n omgekrapte maag kan kry.
- Die tablette moet heel ingesluk word met 'n glas water.

Hou aan om **VIGLYMAK PLUS** elke dag te neem vir so lank as wat jou dokter jou sê om dit te doen. Jy sal moontlik op hierdie behandeling moet bly vir 'n lang tydperk. Jou dokter sal jou toestand gereeld monitor om te kyk of die behandeling die gewenste uitwerking het.
Indien jou dokter vir jou sê om jou behandeling met **VIGLYMAK PLUS** te staak weens lewerprobleme, moet jy nooit weer **VIGLYMAK PLUS** begin neem nie.
Indien jy vrae het oor hoe lank om **VIGLYMAK PLUS** te neem, praat met jou dokter.

Indien jy meer VIGLYMAK PLUS 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 aandag mag nodig wees. Indien jy na 'n dokter of hospitaal moet gaan, neem die pakkie en hierdie inligtingstuk saam.

Indien jy vergeet om VIGLYMAK PLUS te neem
Indien jy vergeet om 'n tablet te neem, neem dit saam met jou volgende maaltyd, tensy jy dan in elk geval een moes neem. Moet nie 'n dubbele dosis (twee tablette gelyktydig) neem om op te maak vir 'n vergete tablet nie.

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

4. Moontlike newe-effekte

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

Indien enige van die volgende gebeur, hou op om **VIGLYMAK PLUS** te neem en lig onmiddellik jou dokter in of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- Swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme met asemhaling of sluk kan veroorsaak
- uitslag of gejeuk
- floute

Hierdie is amal baie ernstige newe-effekte. Indien jy dit het, het jy 'n ernstige reaksie op **VIGLYMAK PLUS** gehad. Jy benodig moontlik dringende mediese aandag of hospitalisering.

Lig onmiddellik jou dokter in of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- melksuur asidose waar simptome van koud en ongemaklik voel, spierpyn, lomerigheid, erge naarheid of braking, abdominale pyn, onverklaarbare gewigsverlies, duiseligheid, onreëlmatige hartklop, of vinnige asemhaling ervaar word
- swak spiere, spierstyfheid, spierpyn en 'n verandering in jou uriene se kleur
- vergeling van die vel en oë, donker uriene en moegheid wat simptome van lewer probleme kan wees

Hierdie is almal baie ernstige newe-effekte. Jy kan moontlik dringende mediese aandag of hospitalisering benodig.

Lig jou dokter in wanneer jy enige van die volgende opmerk:
Gereelde newe-effekte
- naarheid (voel siek),
- abdominale krampe of maagpyn,
- hoofpyn,
- duiseligheid,
- moegheid,
- lighoofdigheid,
- lae bloedsuiker, jy kan moontlik die volgende ervaar: verwarring, honger, naarheid, angs, bewerigheid, hoofpyn of swak voel
- koue rillings
- suur refluks
- tremor
- abnormaal oormatige sweet
- swakheid
- metaalsmaak
- diarree
- verlies aan eetlus

Minder gereelde newe-effekte
- droë hoes,
- spierkrampe,
- winderigheid of winde, hardlywigheid
- diarree,
- neus-, keel- en borskas infeksie
- swelling van die been
- afname in die vlak van vitamien B12 in die bloed (vasgestel deur bloedtoetse)
- lewerprobleme en abnormale lewerfunksie toetsresultate
- uitslag, gejeuk en rooiheid van die vel

Frekwensie onbekend
- Swelling van die pankreas wat ernstige abdominale swelling, opgeblasenheid, verlies van eetlus en koors kan veroorsaak.
- Spierpyn
- Vorming van blase op die vel

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 indien jy enige ongunstige effekte ervaar terwyl jy **VIGLYMAK PLUS** 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 via 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 beskikbaar te stel aangaande die veiligheid van **VIGLYMAK PLUS**.

5. Hoe om VIGLYMAK PLUS te bewaar

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

6. Inhoud van pak en ander inligting

Wat VIGLYMAK PLUS bevat
VIGLYMAK PLUS 50/850
Die aktiewe bestanddele is 50 mg vildagliptien en 850 mg metformienhidrochloried.
VIGLYMAK PLUS 50/1 000
Die aktiewe bestanddele is 50 mg vildagliptien en 1 000 mg metformienhidrochloried.
Suikervry
Die ander bestanddele is:
Hidrokpropielsellulose HPC-L
Mikrokristallyne sellulose Avicel PH 101
Isopropiel alkohol
Magnesiumstearaat
Filmbedekking wat bevat:
HPMC 2910/Hipromellose 6 mPas
Titaandioksied
Makrogol/PEG
Geel ysteroksied
Talk

Hoe VIGLYMAK PLUS lyk en die inhoud van die pak
VIGLYMAK PLUS 50/850: Elke filmbedekte tablet - Geelkleurig, ovaalvormige, bikonvekse, filmbedekte tablet, gegraveer met "F59" aan die een kant en glad aan die ander kant
VIGLYMAK PLUS 50/1 000: Elke filmbedekte tablet – Donkergeel kleurige, ovaalvormige, bikonvekse, filmbedekte tablet, gegraveer met "F60" aan die een kant en glad aan die ander kant.

Inhoud van die pak:
Stulpstrook verpakking:
Tablette word in 'n stulpstrook verpak wat gewone aluminiumfoelie bevat met hitteseëllak as die dekmateriaal en deursigtige PVC/PVDC as die vormingsmateriaal. Die stulpstrook word in 'n buitenste karton verpak.
Stulpstrook verpakking koue vorm:
Tablette word in 'n stulpstrook verpak wat gewone aluminiumfoelie bevat met hitteseëllak as die dekmateriaal en kouevormlaminaat as die vormingsmateriaal. Die stulpstrook word in 'n buitenste karton verpak.

Verpakkingsgroottes sluit 30's, 60's, 120's, 180's en 360'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),
Cussonia-rylaan 1,
Bassonia Rock, Uitbr. 12,
Alberton
Gauteng

Hierdie inligtingstuk is laas hersien in
25 Junie 2025

Registrasienommers
VIGLYMAK PLUS 50/850: 57/21.2/0368.366
VIGLYMAK PLUS 50/1 000: 57/21.2/0369.367

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 PLUS 50/850, 50/1 000 (Vildagliptin and Metformin Hydrochloride 50/850, 50/1 000 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: 350 (L) X 335 (W) mm**			
9. Design / Style: Booklet type		**10. Item code No.: PM04342876**			
11. Artwork has been made: Actual Size		**12. Pharma code No.: 41349 mini**			
13. Barcode/NDC no: NA		**14. Supersedes Item code No: PM04340584**			
15. Revision no: 01		**16. A/W File name:G:\Regulated_Artwork\SOUTH AFRICA\Vildagliptin and Metformin Hydrochloride\SA private Market\01\Vildagliptin and Metformin Hydrochloride 50-1000 mg PIL - PM04342876.cdr**			
Approved By:		**17. Location: Baddi**			
PRD	**M.A. HOLDER**	**RAD**	**QC**	**PRODN**	**QA**
	20/05/2026				

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.

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa - Private Market	PM04340584	29/12/25	Not yet implemented
2) Inclusion of pack sizes (missing information) for better control	PM04342876		