290 mm

**METSITAG**
**50/500**
**50/1 000**
**Tablets**
PM04312101

# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S3

**METSITAG 50/500,**
**METSITAG 50/1 000 Tablets**

Sitagliptin phosphate /metformin hydrochloride
Sugar Free

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


## 1. What METSITAG is and what it is used for

**What METSITAG is:**
**METSITAG** is a tablet that contains two prescription medicines, sitagliptin phosphate and metformin hydrochloride, which lower blood sugar levels. Sitagliptin, a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) and metformin, a member of the biguanide class of medicines, work together along with diet and exercise to control blood sugar levels in patients with type 2 diabetes mellitus. Type 2 diabetes is also called non-insulin dependent diabetes mellitus or Non Insulin Dependant Diabetes Mellitus (NIDDM).

## 2. What you need to know before you take METSITAG

**Do not take METSITAG:**

- If you are allergic to sitagliptin phosphate, metformin hydrochloride or any other components of **METSITAG**, listed in section 6.1
- If you have type 1 diabetes
- If you have certain kidney problems
- If you have a heart problem called congestive heart failure that is treated with medicines
- If you are going to receive an injection of dye or contrast agent for an x-ray procedure. Talk to your doctor about when to stop **METSITAG** and when to start again.
- If you are pregnant or planning to become pregnant.

If you are not sure whether you should take **METSITAG**, contact your doctor.

**Warnings and precautions**
Take special care with **METSITAG**:
Tell your doctor before you get this medicine if.
- You have kidney problems
- You have liver problems
- You have heart problems
- You are older than 80 years. Patients over 80 years should not take **METSITAG** unless their kidney function is checked and normal. Your doctor will monitor your kidney function regularly.
- You have or have had an allergic reaction to sitagliptin, metformin or **METSITAG**
- You are taking any herbal medicines
- You are scheduled for any surgical procedures. You should stop taking **METSITAG** if you are having a procedure and restart 48 hours after the surgery.

**Children and adolescents**
**METSITAG** has not been studied in children under the age of 18 years. Do not give this medicine to children under 18. If **METSITAG** is accidentally ingested by a child, go to the hospital immediately and take the package leaflet with you to show to the emergency doctor

**Other medicines and METSITAG**
Always tell your doctor if you are taking any other medicine. If you are taking your other medicines on a regular basis including complementary and traditional medicines, concomitant use of **METSITAG** may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

**METSITAG** may affect how well other medicines work and some medicines can affect how well **METSITAG** works.

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example, in the context of an X-ray or scan, you must stop taking **METSITAG** before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with **METSITAG**.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of **METSITAG**. It is especially important to mention the following:
- medicines (taken by mouth, inhalation, or injection) used to treat diseases that involve inflammation, like asthma and arthritis (corticosteroids)
- medicines which increase urine production (diuretics)
- 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 (ACE inhibitors and angiotensin II receptor antagonists)
  specific medicines for the treatment of bronchial asthma (β-sympathomimetics)
- iodinated contrast agents or alcohol-containing medicines
- certain medicines used to treat stomach problems such as cimetidine
- ranolazine, a medicine used to treat angina
- dolutegravir, a medicine used to treat HIV infection
- vandetanib, a medicine used to treat a specific type of thyroid cancer (medullary thyroid cancer)
- digoxin (to treat irregular heartbeat and other heart problems). The level of digoxin in your blood may need to be checked if taking with **METSITAG**.

**METSITAG with food, drink and alcohol:**
Avoid excessive alcohol intake while taking **METSITAG** since this may increase the risk of side effects

**Pregnancy, breastfeeding and fertility**
If you are pregnant, or breastfeeding, think you may be pregnant or are planning to become pregnant please consult your doctor, pharmacist or other healthcare provider before taking this medicine.

You should not take **METSITAG** if you are pregnant or breastfeeding.

**Driving and using machines**
There is no information to suggest that **METSITAG** affects your ability to drive a car or operate machinery.
It is not always possible to predict to what extent **METSITAG** 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 **METSITAG** affects you.

## 3. How to take METSITAG

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

Always take **METSITAG** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of **METSITAG** is too strong or too weak, talk to your doctor or pharmacist
- Take **METSITAG** exactly as your doctor has prescribed. Your doctor will tell you how many **METSITAG** tablets to take and how often you should take them.
- Your doctor may need to increase your dose to control your blood sugar levels.
- Your doctor may prescribe **METSITAG** along with a sulphonylurea (another medicine to lower blood sugar levels)
- Take **METSITAG** with meals to lower your chance of an upset stomach.
- Continue to take **METSITAG** as long as your doctor prescribes it so you can continue to help control your blood sugar levels.

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

**If you forget to take METSITAG**
If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to a regular schedule. Do not take a double dose to make up for forgotten individual doses.

## 4 Possible side effects

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

If any of the following happens, stop taking **METSITAG** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Allergic reactions, which may be serious including rash, hives, and swelling of the face, lips, tongue and throat may cause difficulty breathing or swallowing.

These are all very serious side effects. If you have them, you have had a serious reaction to **METSITAG**. You may need urgent attention or hospitalisation.
Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Feeling sick (nausea) or being sick (vomiting), abdominal pain, muscular cramps, unexplained weight loss, rapid breathing and feeling cold or uncomfortable. In rare cases, metformin, one of the medicines in **METSITAG**, can cause a serious side effect called lactic acidosis (too much lactic acid in your blood). This is more common in people whose kidneys are not working properly. Lactic acidosis is a medical emergency that can cause death and must be treated in the hospital. Stop taking **METSITAG** if you get any of the above symptoms of lactic acidosis and see your doctor immediately.
- Severe and persistent stomach pain, often with nausea and vomiting. These may be symptoms of pancreatitis. Pancreatitis can be serious, potentially life-threatening medical condition. Stop taking **METSITAG** and call your doctor right away if you experience these symptoms

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
- Low blood sugar
- Nausea
- Vomiting
- Flatulence
- Loss of appetite
- A metallic taste

Less frequent side effects
Tell your doctor if you notice any of the following:
- Abdominal pain
- Diarrhoea
- Constipation
- Drowsiness
- Dizziness
- Decreased vitamin B12 levels
- Redness of the skin (rash) or itching.
- Changes in how much urine you pass, swelling of ankles and feet due to fluid retention (these may indicate a problem with your kidneys).
- Headache
- Inflammation and scarring to your lungs (you may experience shortness of breath, cough, extreme tiredness and weakness.
- Fluid filled blisters in creases of the skin.
- Arm or leg pain
- Painful joint disease most frequently affecting hips, knees and spine.

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 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 **Adverse drug reaction and quality 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 **METSITAG**.

## 5. How to store METSITAG

Store in the original packaging at or below 25 °C.
Keep the blisters in the carton until required for use.
Keep the HDPE container tightly closed.
Store in the original package in order to protect from light and moisture.
KEEP OUT OF THE REACH OF CHILDREN.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister/carton.
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 METSITAG contains**
**METSITAG 50/500:** Each tablet contains 50 mg Sitagliptin as phosphate and 500 mg metformin hydrochloride.
**METSITAG 50/1 000:** Each tablet contains 50 mg Sitagliptin as phosphate and 1 000 mg metformin hydrochloride.
**METSITAG** is sugar free
Other ingredients include:
The inactive ingredients are: Microcrystalline cellulose, Povidone, Sodium lauryl sulfate, Croscarmellose Sodium, Sodium stearyl fumarate. In addition, film-coating contains the following inactive ingredient: Hypromellose, Polyethylene glycol 400, Polyethylene glycol 6000, Talc, Titanium dioxide, Red iron oxide, Yellow iron oxide.

**What METSITAG looks like and contents of the pack**
**METSITAG 50/500:** Light pink colour capsule shape, biconvex film coated tablets, debossed with "C 77" on one side and plain on the other side.
**METSITAG 50/1 000:** Red colour capsule shape, biconvex, film coated tablets, debossed with "C 78" on one side and plain on the other side.

**Contents of the pack:**
**METSITAG** tablets are packed in cold form (Alu-Alu) Blister pack of 10's, 14's, 28's, 56's and HDPE container pack of 60's.
Not all packs and pack sizes are necessarily 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**
21 November 2023

**Registration numbers**
**METSITAG 50/500:** 56/21.2/0317
**METSITAG 50/1 000:** 56/21.2/0318

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

335 mm

290 mm

335 mm

**PASIËNTINLIGTINGSTUK**

**SKEDULERINGSTATUS:** S3

**METSITAG 50/500,**
**METSITAG 50/1 000 Tablette**

**Sitagliptienfosfaat/metformienhidrochloried**
**Suikervry**

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


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

**Wat METSITAG is:**
**METSITAG** is 'n tablet wat twee voorskrifmiddels bevat, sitagliptienfosfaat en metformienhidrochloried, wat bloedsuikervlakke verlaag. Sitagliptien, 'n lid van 'n klas van medisyne genaamd DPP-4-inhibeerders (dipeptidielpeptidase-4-inhibeerders) en metformien, 'n lid van die biguaniedklas van medisyne, wat saamwerk met dieet en oefening om bloedsuikervlakke in pasiënte met tipe 2 diabetes mellitus te beheer. Tipe 2 diabetes word ook nie-insulien afhanklike diabetes mellitus of Nie Insulien Afhanklike Diabetes Mellitus (NIADM) genoem.

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

**Moet nie METSITAG neem nie:**
- Indien jy allergies is vir sitagliptienfosfaat, metformienhidrochloried of enige ander komponente van **METSITAG**, gelys in afdeling 6.1
- Indien jy tipe 1 diabetes het
- Indien jy sekere nierprobleme het
- Indien jy 'n hartprobleem het wat kongestiewe hartversaking genoem word wat met medisyne behandel word
- Indien jy 'n inspuiting van kleurstof of kontrasmiddel vir 'n x-straal prosedure gaan ontvang. Praat met jou dokter oor wanneer om met **METSITAG** te stop en wanneer om weer te begin.
- Indien jy swanger is of beplan om swanger te raak.

As jy nie seker is of jy **METSITAG** moet neem of nie, kontak jou dokter.

**Waarskuwings en voorsorgmaatreëls**
Neem spesiale sorg met **METSITAG**:
Vertel jou dokter, voordat jy hierdie medisyne ontvang, indien.
- Jy nierprobleme het
- Jy lewerprobleme het
- Jy hartprobleme het
- Jy ouer as 80 jaar oud is. Pasiënte ouer as 80 jaar oud moet nie **METSITAG** neem nie, tensy hulle nierfunksie nagegaan, en normaal is. Jou dokter sal jou nierfunksie gereeld monitor.
- Jy tans, of al voorheen 'n allergiese reaksie op sitagliptien, metformien of **METSITAG** gehad het
- Jy enige kruiemedisyne neem
- Jy geskeduleer is vir enige chirurgiese prosedures. Indien jy 'n prosedure ondergaan moet jy ophou om **METSITAG** te neem en eers weer 48 uur na die operasie begin.

**Kinders en adolessente**
**METSITAG** is nie in kinders onder die ouderdom van 18 jaar oud bestudeer nie. Moet nie hierdie medisyne aan kinders jonger as 18 gee nie. Indien **METSITAG** per ongeluk deur 'n kind ingeneem word, gaan onmiddellik hospitaal toe en neem die inligtingstuk saam om aan die ongevalle dokter te wys

**Ander medisyne en METSITAG**
Vertel altyd vir jou dokter indien jy enige ander medisyne neem. Indien jy jou ander medisyne op 'n gereelde basis neem, insluitend komplementêre en tradisionele medisyne, kan die gelyktydige gebruik van **METSITAG** ongewenste interaksies veroorsaak. Raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

**METSITAG** kan beïnvloed hoe goed ander medisyne werk en sommige medisyne kan beïnvloed hoe goed **METSITAG** werk.

Indien jy 'n inspuiting in jou bloedstroom moet kry van 'n kontrasmedium wat jodium bevat, byvoorbeeld in die konteks van 'n X-straal of skandering, moet jy ophou om **METSITAG** te neem, voor, of tydens die inspuiting. Jou dokter sal besluit wanneer jy moet stop en wanneer om jou behandeling met **METSITAG** weer te begin.
Vertel jou dokter of apteker as jy enige ander medisyne neem, onlangs geneem het of dalk gaan neem. Jy sal moontlik meer gereelde bloedglukose- en nierfunksietoetse nodig hê, of jou dokter sal moontlik die dosis van **METSITAG** moet aanpas. Dit is veral belangrik om die volgende te noem:
- medisyne (mondelings geneem, inhalasie of inspuiting) wat gebruik word om siektes te behandel wat inflammasie behels, soos asma en artritis (kortikosteroïede)
- medisyne wat urienproduksie verhoog (diuretikum)
- 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 (ACE inhibeerders en angiotensien II reseptor antagoniste)
- spesifieke medisyne vir die behandeling van brongiale asthma (β-simpatomimetikum)
- jodiumbevattende kontrasmiddels of alkoholbevattende medisyne
- sekere medisyne, soos simetidien, wat gebruik word om maagprobleme te behandel
- ranolasien, 'n medisyne wat gebruik word om angina te behandel.
- dolutegravir, 'n medisyne wat gebruik word om MIV infeksie te behandel
- vandetanib, 'n medisyne wat gebruik word om 'n spesifieke tipe skildklierkanker (medullêre tiroïedkanker) te behandel.
- digoksien (om onreëlmatige hartklop en ander hartprobleme te behandel). Die vlak van digoksien in jou bloed sal moontlik nagegaan moet word wanneer jy dit saam met **METSITAG** neem.

**METSITAG met voedsel, vloeistof en alkohol:**
Vermy oormatige alkohol inname terwyl **METSITAG** geneem word, aangesien dit die risiko van newe-effekte kan verhoog

**Swangerskap, borsvoeding en fertiliteit**
Indien jy swanger is, of borsvoed, vermoed dat jy moontlik swanger is, of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy hierdie medisyne neem.

Jy moet nie **METSITAG** neem indien jy swanger is of borsvoed nie.

**Bestuur en gebruik van masjinerie**
Daar is geen inligting wat daarop dui dat **METSITAG** jou vermoë om 'n motor te bestuur of masjinerie te hanteer, beïnvloed nie.
Dit is nie altyd moontlik om te voorspel tot watter mate **METSITAG** met jou daaglikse aktiwiteite kan inmeng nie. Jy moet seker maak dat jy nie by die bogenoemde aktiwiteite betrokke raak totdat jy bewus is van die mate waartoe **METSITAG** jou affekteer nie.

## 3. Hoe om METSITAG te neem

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

Neem altyd **METSITAG** presies soos wat jou dokter dit vir jou voorgeskryf het. Jy moet met jou dokter of apteker bevestig indien jy nie seker is nie.

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

- Neem **METSITAG** presies soos jou dokter dit voorgeskryf het. Jou dokter sal vir jou sê hoeveel **METSITAG** tablette jy moet neem en hoe gereeld jy dit moet neem.
- Jou dokter sal moontlik jou dosis moet verhoog om jou bloedsuikervlakke te beheer.
- Jou dokter kan **METSITAG** saam met 'n sulfonielureum voorskryf ('n ander middel om bloedsuikervlakke te verlaag)
- Neem **METSITAG** saam met etes om jou kans op 'n omgekrapte maag te verminder.
- Gaan voort om **METSITAG** te neem vir solank as wat jou dokter dit voorskryf sodat jy kan voortgaan om jou bloedsuikervlakke te help beheer.

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

**Indien jy vergeet om METSITAG te neem**
Indien jy 'n dosis oorslaan, neem dit so gou as wat jy daarvan onthou. Indien jy nie onthou nie, totdat dit tyd is vir jou volgende dosis, slaan die dosis wat jy vergeet het oor en gaan terug na 'n gereelde skedule. Moet nie 'n dubbele dosis neem om op te maak vir die individuele dosis wat jy vergeet het nie.

## 4 Moontlike newe-effekte

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

Indien enige van die volgende gebeur, hou op om **METSITAG** te neem en lig onmiddellik jou dokter in of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- Allergiese reaksies, wat ernstig kan wees, insluitend uitslag, galbulte en swelling van die gesig, lippe, tong en keel, wat probleme met asemhaling of sluk kan veroorsaak.

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, het jy 'n ernstige reaksie op **METSITAG** gehad. Jy benodig moontlik dringende hulp of hospitalisasie.
Lig onmiddellik jou dokter in of gaan na die ongevalle-afdeling van jou naaste hospitaal as jy enige van die volgende opmerk:
- Voel siek (naarheid) of is siek (braking), abdominale pyn, spierkrampe, onverklaarbare gewigsverlies, vinnige asemhaling en voel koud of ongemaklik. In seldsame gevalle kan metformien, een van die middels in **METSITAG**, 'n ernstige newe-effek veroorsaak wat melksuurasidosis genoem word (te veel melksuur in jou bloed). Dit is meer algemeen in mense wie se niere nie behoorlik werk nie. Melksuurasidosis is 'n mediese noodgeval wat die dood kan veroorsaak en moet in die hospitaal behandel word. Hou op om **METSITAG** te neem indien jy enige van die bogenoemde simptome van melksuurasidosis kry en gaan sien onmiddellik jou dokter.
- Erge en aanhoudende maagpyn, dikwels met naarheid en braking. Hierdie kan simptome van pankreatitis wees. Pankreatitis kan 'n ernstige, potensieel lewensgevaarlike mediese toestand wees. Hou op om **METSITAG** te neem en skakel onmiddellik jou dokter indien jy hierdie simptome ervaar

Hierdie is almal baie ernstige newe-effekte. Jy moet dalk dringende mediese hulp of hospitalisasie kry.

Lig jou dokter in wanneer jy enige van die volgende opmerk:
Gereelde newe-effekte
- Lae bloedsuiker
- Naarheid
- Braking
- Winderigheid
- Verlies aan eetlus
- 'n Metaalsmaak

Minder gereelde newe-effekte
Lig jou dokter in wanneer jy enige van die volgende opmerk:
- Abdominale pyn
- Diaree
- Hardlywigheid
- Lomerigheid
- Duiseligheid
- Verlaagde vitamien B12-vlakke
- Rooiheid van die vel (uitslag) of jeuk.
- Veranderinge in hoeveel uriene wat jy passeer, swelling van enkels en voete as gevolg van vloeistofretensie (hierdie kan 'n aanduiding wees dat daar 'n probleem met jou niere is).
- Hoofpyn
- Ontsteking en littekens aan jou longe (jy kan kort van asem, hoes, uiterste moegheid en swakheid ervaar).
- Vloeistofgevulde blase in plooie van die vel.
- Arm- of beenpyn
- Pynlike gewrigsiekte wat meer gereeld die heupe, knieë en ruggraat aantas.

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

**Rapportering van newe-effekte**
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **Adverse drug reactions and quality 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 te verskaf oor die veiligheid van **METSITAG**.

## 5. Hoe om METSITAG te stoor

Berg in die oorspronklike verpakking by of benede 25 °C.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Hou die HDPE-houer dig toe.
Berg in die oorspronklike verpakking om sodoende teen lig en vog te beskerm.
HOU BUITE DIE BEREIK VAN KINDERS.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat aangebring is op die stulpstrook/karton nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

## 6. Inhoud van pakkie en ander inligting

**Wat METSITAG bevat**
**METSITAG 50/500:** Elke tablet bevat 50 mg Sitagliptien as fosfaat en 500 mg metformienhidrochloried.
**METSITAG 50/1 000:** Elke tablet bevat 50 mg Sitagliptien as fosfaat en 1 000 mg metformienhidrochloried.
**METSITAG** is suikervry
Ander bestanddele sluit in:
Die onaktiewe bestanddele is: Mikrokristallyne sellulose, Povidoon, Natriumlaurielsulfaat, Natriumkruiskarmellose, Natriumstearielfumaraat. Daarbenewens bevat die filmbedekking die volgende onaktiewe bestanddele : Hipromelose, Poliëtileenglikol 400, Poliëtileenglikol 6 000, Talk, Titaandioksied, Rooi ysteroksied, Geel ysteroksied.

**Hoe lyk METSITAG en die inhoud van die pakkie**
**METSITAG 50/500:** Ligte pienk kleurige kapsuul vormige, bikonvekse filmbedekte tablette, gemerk met "C 77" aan die een kant en glad aan die ander kant.
**METSITAG 50/1 000:** Rooi gekleurde kapsuul vormige, bikonvekse, filmbedekte tablette, gemerk met "C 78" aan die een kant en glad aan die ander kant.

**Inhoud van die pakkie:**
**METSITAG** tablette word verpak in koue vorm (Alu-Alu) stulpverpakking van 10's, 14's, 28's, 56's en HDPE-houerpak van 60's.
Nie alle verpakkings en 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**
21 November 2023

**Registrasienommers**
**METSITAG 50/500:** 56/21.2/0317
**METSITAG 50/1 000:** 56/21.2/0318

**Vir die ooreenstemmende Professionele Inligting**
Die ooreenstemmende professionele inligting kan by https://macleodssaproducts.co.za/ verkry word of deur 011 682 1169 te kontak

MASTER COPY

MACLEODS

PACKAGING RESEARCH & DEVELOPMENT

*Restricted Circulation*

(Front Page)

## ARTWORK / PRINTPROOF APPROVAL FORM

| | |
|---|---|
| 1. Product: METSITAG 50/500, 50/1 000 mg (Metformin & Sitagliptin Tablets 50/500, 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: 335(L) X 290(W) mm |
| 9. Design / Style: Booklet type | 10. Item code No.: PM04312101 |
| 11. Artwork has been made: Actual Size | 12. Pharma code No.: 33578 mini |
| 13. Barcode/NDC no: NA | 14. Supersedes Item code No: NA |
| 15. Revision no: 00 | 16. A/W File name:Z:\Metformin and Sitagliptin\62\Metformin hydrochloride and Sitagliptin PIL - PM04312101.cdr |
| Approved By: | 17. Location: Baddi |

| PRD | M.A. HOLDER | RAD | QC | PRODN | QA |
|---|---|---|---|---|---|
| 16/05/2024 | Vanita Rajool | 07/05/24 | 17/05/24 | 17.05.24 | 21.05.24 |

**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 | PM04312101 | | |

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