Front Side

330 mm

SENTALIS
5/20 MG
(film-coated tablet)
PM03991503

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

SENTALIS 5 mg Tadalafil
SENTALIS 20 mg Tadalafil

Contains lactose:
Each 5 mg film coated tablet contains 50 mg lactose (as monohydrate).
Each 20 mg film coated tablet contains 200 mg lactose (as monohydrate).

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

1. What SENTALIS is and what it is used for

SENTALIS contains the active substance tadalafil.
SENTALIS is a treatment for men with erectile dysfunction. This when a man cannot get or keep a hard, erect penis suitable for sexual activity.
Tadalafil belongs to a group of medicines called phosphodiesterase type 5 inhibitors.
Following sexual stimulation tadalafil works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. The result of this is an improved erection. Tadalafil will not help you if you do not have erectile dysfunction. It is important to note that tadalafil for the treatment of erectile dysfunction does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking any medicines for erectile dysfunction.

2. What you need to know before you take SENTALIS

Do not take SENTALIS:
- if you are hypersensitive (allergic) to tadalafil or any of the other ingredients of **SENTALIS** (listed in section 6.1)
- if you are taking any form of a group of medicines called nitrates. These are used in the treatment of angina.
- if you have serious heart disease or recently had a heart attack within the last 90 days.
- recently had a stroke within the last 6 months.
- have low blood pressure or uncontrolled high blood pressure.
- have a severe hepatic (liver) insufficiency (Child-Pugh Class C).
- If you have ever had loss of vision because of a condition called non-arteritic anterior ischemic optic neuropathy (NAION), also described as “stroke of the eye”. This may or may not have been connected to taking a medicine like tadalafil.
- If you have previously experienced loss of hearing in one or both ears, with or without symptoms like vertigo and dizziness.

Warnings and precautions
Tell your doctor if you have a history of heart disease. Be aware that sexual activity carries a possible risk to patients with heart disease because it puts an extra strain on your heart.

Take special care with **SENTALIS:**
- If you are taking medicines to control your blood pressure as the dosage of these medicines might have to be adjusted to prevent your blood pressure from dropping too low.
- if you notice any symptoms or feel any discomfort when you begin sexual activity, stop immediately and report the incident to your doctor.
- And let your doctor know immediately if you experience sudden loss of vision or any change in vision.
- And let your doctor know immediately if you experience a sudden loss of hearing or decrease in ability to hear. You may experience dizziness and ringing in your ears with this loss of hearing.
- If you have kidney or liver disease
- If you experience prolonged erections (4 hours or more) while taking tadalafil. If this is not treated immediately it can lead to permanent damage and loss of potency.
- If you have any malformations of the penis
- If you suffer from a type of anaemia called sickle cell anaemia or any type of cancer.
- If you are taking other medication for erectile dysfunction as **SENTALIS** should not be taken with certain other medicines (see section “Other medicines and **SENTALIS**” below).

It is not known if **SENTALIS** is effective in patients who have had
- pelvic surgery
- removal of all or part of the prostate gland in which nerves of the prostate are cut (radical non nerve-sparing praostatectomy).

Children and adolescents
SENTALIS is not intended for use by children and adolescents under age 18.

Other medicines and SENTALIS
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
Please talk to your doctor or pharmacist if you are taking any of the following medicines:
- Medicines to control your blood pressure
- Ketoconazole, itraconazole (used to treat fungal infections)
- Rifampicin (used to treat tuberculosis)
- Medicines used for the treatment and control of seizures (fits)
- Ritonavir, saquinavir (used in the treatment of HIV/AIDS)
- Antacids (used to neutralise acid in the stomach)

SENTALIS with food and drink
- **SENTALIS** may be taken with or without food.
- Grapefruit juice may affect how well **SENTALIS** will work and should be taken with caution.
- Drinking alcohol may affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or are planning to take **SENTALIS**, avoid excessive drinking (blood alcohol level of 0,08 % or greater), since this may increase the risk of dizziness when standing up.

Pregnancy, breastfeeding and fertility
- **SENTALIS** is not indicated for use in women. If you and your partner are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.
- You should not use this medicine during pregnancy.
- You should not breast-feed while using **SENTALIS**.

Driving and using machines
You may experience dizziness while using **SENTALIS**.
It is not always possible to predict to what extent **SENTALIS** may interfere with the daily activities of a patient.
Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **SENTALIS** affects them.

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

- Do not share medicines prescribed for you with any other person.
- Always take **SENTALIS** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- The usual dose is 5 mg daily at approximately the same time of day.
- The maximum dose is 20 mg a day.
- You should not take **SENTALIS** more than once in a day.
- **SENTALIS 20 mg** may be taken up to 36 hours or as early as 16 minutes prior to when you want to engage in sexual activity.
- Swallow the tablet whole with a glass of water.
- If you have the impression that the effect of **SENTALIS** is too strong or too weak, tell your doctor or pharmacist.

If you take more SENTALIS than you should
In the event of overdosage consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison centre. You may experience headache, discomfort in your stomach, back or muscle pain and an erection that lasts longer than 4 hours.

If you forget to take SENTALIS
If you forget to take **SENTALIS**, take it as soon as you remember. Do not take a double dose to make up for forgotten doses. You should not take **SENTALIS** more than once in a day.

4. Possible side effects

SENTALIS can have side effects.
Not all side effects reported for **SENTALIS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **SENTALIS**, please consult your doctor, pharmacist or other healthcare professional for advice.
- If any of the following happens, stop taking **SENTALIS** and tell your doctor immediately or go to the casualty department at your nearest hospital:
  - Difficulty breathing
  - Severe skin rash or itching
  - Swollen tongue or lips

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

- Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
  - Chest pain
  - An erection that lasts longer than 4 hours
  - Sudden loss of vision

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

- Tell your doctor if you notice any of the following:
  - <u>Frequent side effects</u>
    - Headache
    - Reddening of the face (flushing)
    - Stuffy nose
    - Discomfort in your stomach
    - Back pain, pain in your muscles or any part of your body
  - <u>Less frequent side effects</u>
    - Dizziness
    - Loss of consciousness or numbness on one side of the body
    - Fainting, severe headache (migraine), sudden memory loss
    - Blurred vision or loss of vision, eye pain, swelling of eyelids, redness or itching of the eye
    - Ringing in ears, loss of hearing
    - Changes in heart rhythm, chest pain or feeling of pressure in chest
    - Low or high blood pressure
    - Difficulty breathing, nose bleeds
    - Stomach pain, nausea, vomiting, heartburn or burning sensation in your throat
    - Rash, sweating
    - Blood in urine
    - Prolonged erections, blood in the sperm or bleeding from the penis
    - Chest pain, tiredness, swelling of the legs or face
  - Frequency unknown
    - Retinal detachment (which may appear as tiny specks through your field of vision).

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 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 **SENTALIS**.

5. How to store SENTALIS

Store at or below 25 ℃ (room temperature).
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 / 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 the pack and other information

What SENTALIS contains
Each film coated tablet contains 5 mg or 20 mg tadalafil.
Other ingredients include:
Tablet core contains:
Croscarmellose sodium, microcrystalline cellulose, lactose monohydrate, colloidal silicon dioxide, povidone, sodium lauryl sulphate, sodium citrate dihydrate, sodium stearyl fumarate.
Film coating contains:
Hypromellose (E464), triacetin (E1518), talc (E553b), titanium dioxide (E171), iron oxide yellow (E172).

What SENTALIS looks like and contents of the pack
SENTALIS 5 mg:
Yellow coloured, almond shaped, biconvex film coated tablets having 'L 62' debossed on one side and plain on other side.
SENTALIS 20 mg:
Yellow coloured, almond shaped, biconvex film coated tablets having 'L 64' debossed on one side and plain on other side.

Contents of the pack:
HDPE Container Pack:
Tablets are packed in round, white HDPE container with child resistant closure with pulp and heat seal liner.
Pack size include 30's tablets.
Blister Pack:
Tablets are packed in clear PVC / PVdC foil as the forming material and plain aluminium foil with heat seal lacquer as the lidding material.
Pack size include:
SENTALIS 5 mg – Pack size include 10's, 14's, 28's or 100's tablets.
SENTALIS 20 mg - Pack size include 2's, 4's, 8's, 10's or 100's tablets.
Not all pack sizes are necessarily marketed.

HOLDER OF CERTIFICATE OF REGISTRATION
Macleods Pharmaceuticals SA (Pty) Ltd
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

This leaflet was last revised in
26 February 2024

Registration number
SENTALIS 5 MG : 49/7.1.5/1147
SENTALIS 20 MG : 49/7.1.5/1148

Access to the corresponding Professional Information
The corresponding professional information can be accessed at macleodssaproducts.co.za or contact 011 6821169

235 mm

Back Side

330 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

SENTALIS 5 mg Tadalafil
SENTALIS 20 mg Tadalafil

Bevat laktose:
Elke 5 mg filmbedekte tablet bevat 50 mg laktose (as monohidraat).
Elke 20 mg filmbedekte tablet bevat 200 mg laktose (as monohidraat).

Lees hierdie hele inligtingstuk noukeurig deur voordat jy SENTALIS 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.
- **SENTALIS** is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hul simptome dieselfde as joune.

Wat in hierdie inligtingstuk is

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

1. Wat SENTALIS is en waarvoor dit gebruik word

SENTALIS bevat die aktiewe bestanddeel tadalafil.
SENTALIS is 'n behandeling vir mans met erektiele disfunksie. Dit is wanneer 'n man nie 'n harde, regop penis kan kry, of hou, wat geskik is vir seksuele aktiwiteit nie.
Tadalafil behoort aan 'n groep van medisyne wat fosfodiesterase tipe 5 inhibeerders genoem word.
Na seksuele stimulasie werk tadalafil deur die bloedvate in jou penis te help om te ontspan, wat die vloei van bloed in jou penis toelaat. Die gevolg hiervan is 'n verbeterde ereksie. Tadalafil sal jou nie help as jy nie erektiele disfunksie het nie. Dit is belangrik om daarop te let dat tadalafil nie werk vir die behandeling van erektiele disfunksie, as daar geen seksuele stimulasie is nie. Jy en jou maat sal voorspel moet geniet, net soos jy sou doen as jy geen medisyne vir erektiele disfunksie geneem het nie.

2. Wat jy behoort te weet voordat jy SENTALIS neem

Moet nie SENTALIS neem:
- indien jy hipersensitief (allergies) vir tadalafil of enige van die ander bestanddele van **SENTALIS** is nie (gelys in afdeling 6).
- indien jy enige vorm van 'n groep medisyne bekend as nitrate gebruik nie. Dit word gebruik in die behandeling van angina.
- indien jy ernstige hartsiekte het of onlangs, binne die afgelope 90 dae, 'n hartaanval gehad het.
- Onlangs, in die afgelope 6 maande, 'n beroerte gehad het.
- lae bloeddruk of onbeheerde hoë bloeddruk het.
- 'n ernstige hepatiese (lewer) ontoereikendheid het (Child-Pugh Klas C).
- Indien jy al ooit verlies aan visie gehad het as gevolg van 'n toestand bekend as nie-arteritiese anterior isgemiese optiese neuropatie (NAION), ook beskryf as "beroerte van die oog". Dit kan, of kan nie, verband hou met die neem van 'n middel soos tadalafil.
- Indien jy voorheen gehoorverlies in een of albei ore ervaar het, met of sonder simptome soos vertigo en duiseligheid.

Waarskuwings en voorsorgmaatreëls
Vertel jou dokter as jy 'n geskiedenis van hartsiektes het. Wees bewus daarvan dat seksuele aktiwiteit 'n moontlike risiko vir pasiënte met hartsiektes inhou, omdat dit 'n ekstra spanning op jou hart plaas.

Neem spesiale sorg met **SENTALIS**:
- Indien jy medisyne neem om jou bloeddruk te beheer, aangesien die dosis van hierdie medisyne dalk aangepas moet word om te voorkom dat jou bloeddruk te laag daal.
- indien jy enige simptome opmerk of enige ongemak voel wanneer jy met seksuele aktiwiteit begin, stop onmiddellik en rapporteer die voorval by jou dokter.
- En laat onmiddellik jou dokter weet as jy skielike verlies van visie of enige verandering in visie ervaar.
- En laat onmiddellik jou dokter weet as jy 'n skielike gehoorverlies of afname in die vermoë om te kan hoor, ervaar. Jy kan duiseligheid en suising in jou ore ervaar met hierdie gehoorverlies.
- Indien jy nier- of lewersiekte het
- Indien jy langdurige ereksies (4 ure of langer) ervaar terwyl jy tadalafil neem. As dit nie dadelik behandel word nie, kan dit lei tot permanente skade en verlies aan vermoë.
- Indien jy enige misvormings van die penis het
- Indien jy ly aan 'n tipe bloedarmoede naamlik sekelsel anemie of enige tipe kanker.
- Indien jy ander medikasie vir erektiele disfunksie neem, aangesien **SENTALIS** nie saam met sekere ander medisyne geneem moet word nie (sien afdeling "Ander medisyne en **SENTALIS**" hieronder).

Dit is nie bekend of **SENTALIS** effektief is in pasiënte wat die volgende gehad het nie
- bekkenchirurgie
- verwydering van die hele, of 'n deel, van die prostaatklier waar senuwees van die prostaat gesny is (radikale nie-senuwee-besparende prostatektomie).

Kinders en adolessente
SENTALIS is nie bedoel vir gebruik deur kinders en adolessente jonger as 18 jarige ouderdom nie.

Ander medisyne en SENTALIS
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Praat asseblief met jou dokter of apteker as jy enige van die volgende medisyne gebruik:
- Medisyne om jou bloeddruk te beheer
- Ketokonasool, itrakonasool (gebruik om swaminfeksies te behandel)
- Rifampisien (gebruik om tuberkulose te behandel)
- Medisyne wat gebruik word vir die behandeling en beheer van aanvalle (stuiptrekkings)
- Ritonavir, sakwinavir (gebruik in die behandeling van MIV/VIGS)
- Teensuurmiddels (gebruik om suur in die maag te neutraliseer)

SENTALIS met voedsel en vloeistof
- **SENTALIS** kan met of sonder kos geneem word.
- Pomelosap kan beïnvloed hoe goed **SENTALIS** sal werk, en moet met omsigtigheid geneem word.
- Die drink van alkohol kan jou vermoë om 'n ereksie te kry beïnvloed en kan jou bloeddruk tydelik verlaag. Indien jy **SENTALIS** geneem het of beplan om dit te neem, vermy oormatige inname (bloedalkoholvlak van 0,08 % of meer), aangesien dit die risiko van duiseligheid kan verhoog wanneer jy op staan.

Swangerskap, borsvoeding en fertiliteit
- **SENTALIS** is nie aangedui vir gebruik deur vrouens nie. Indien jy en jou maat beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne neem.
- Jy moet nie hierdie medisyne tydens swangerskap gebruik nie.
- Jy moet nie borsvoed terwyl jy **SENTALIS** gebruik nie.

Bestuur en gebruik van masjinerie
Jy kan duiseligheid ervaar terwyl jy **SENTALIS** gebruik.
Dit is nie altyd moontlik om te voorspel tot watter mate **SENTALIS** met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie.
Pasiënte moet seker maak dat hulle nie by bogenoemde aktiwiteite betrokke raak nie, totdat hulle bewus is van die mate waarin **SENTALIS** hulle affekteer.
.
SENTALIS bevat laktose
Indien jou dokter vir jou gesê het dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy hierdie medisyne neem.

SENTALIS bevat natrium
Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per tablet, dit wil sê in wese 'natriumvry'.

3. Hoe om SENTALIS te neem

- Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
- Neem altyd **SENTALIS** presies soos jou dokter of apteker vir jou gesê het. Vra vir jou dokter of apteker indien jy onseker is.
- Die gewone dosis is 5 mg daagliks, op ongeveer dieselfde tyd van die dag.
- Die maksimum dosis is 20 mg per dag.
- Jy moet nie **SENTALIS** meer as een keer per dag neem nie.
- **SENTALIS 20 mg** kan geneem word tot 36 ure, of so vroeg as 16 minute, voor wanneer jy aan seksuele aktiwiteit wil deelneem.
- Sluk die tablet heel met 'n glas water.
- Indien jy die indruk het dat die effek van **SENTALIS** te sterk of te swak is, vertel jou dokter of apteker.

Indien jy meer SENTALIS neem as wat jy behoort te neem
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Jy kan hoofpyn, ongemak in jou maag, rug- of spierpyn ervaar en 'n ereksie wat langer as 4 ure duur.

Indien jy vergeet om SENTALIS te neem
Indien jy vergeet om **SENTALIS** te neem. Neem dit so gou as wat jy onthou. Moet nie 'n dubbele dosis neem om vir vergete dosisse op te maak nie. Jy moet nie **SENTALIS** meer as een keer per dag neem nie.

4. Moontlike newe-effekte

SENTALIS kan newe-effekte hê.
Nie alle newe-effkte wat vir **SENTALIS** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige ongunstige effekte ervaar terwyl jy **SENTALIS** neem, kontak asseblief jou dokter, apteker, of ander professionele gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, hou op om **SENTALIS** te neem en sê onmiddellik vir jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- Moeilike asemhaling
- Erge vel uitslag of gejeuk
- Geswelde tong of lippe

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

Vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:
- Borskaspyn
- 'n Ereksie wat langer as 4 ure duur
- Skielike verlies van visie

Hierdie is alles ernstige newe-effekte. Jy benodig dalk dringende mediese hulp

Vertel jou dokter as jy enige van die volgende opmerk:
<u>Gereelde newe-effekte</u>
- Hoofpyn
- Rooi wording van die gesig (blosing)
- Toe neus
- Ongemak in jou maag
- Rugpyn, pyn in jou spiere of enige deel van jou liggaam

<u>Minder gereelde newe-effekte:</u>
- Duiseligheid
- Verlies van bewussyn of gevoelloosheid aan die een kant van die liggaam
- Floutes, erge hoofpyn (migraine), skielike geheueverlies
- Dowwe visie of verlies van visie, oogpyn, swelling van ooglede, rooiheid of jeuk van die oog
- Gesuis in ore, gehoorverlies
- Veranderinge in hartritme, borskaspyn of gevoel van druk in die bors
- Lae of hoë bloeddruk
- Asemhalingsprobleme, neus bloeding
- Maagpyn, naarheid, braking, sooibrand of brandende sensasie in jou keel
- Uitslag, sweet
- Bloed in uriene
- Langdurige ereksies, bloed in die sperm of bloeding vanaf die penis
- Borskaspyn, moegheid, swelling van die bene of gesig

<u>Frekwensie onbekend</u>
Retinale loslating (wat kan lyk soos klein spikkels in jou gesigsveld)

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

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter 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. safety@macleodspharma.com. Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **SENTALIS.**

5. Hoe om SENTALIS te bewaar

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

6. Inhoud van die pak en ander inligting

Wat SENTALIS bevat
Elke filmbedekte tablet bevat 5 mg of 20 mg tadalafil.
Ander bestanddele sluit in:
Tabletkern bevat:
Natriumkruiskarmellose, mikrokristallyne sellulose, laktosemonohidraat, kolloïdale silikondioksied, povidoon, natriumlaurielsulfaat, natriumsitraatdihidraat, natriumstearielfumaraat.
Filmbedekking bevat:
Hipromellose (E464), triasetien (E1518), talk (E553b), titaandioksied (E171), geel ysteroksied (E172).

Hoe SENTALIS lyk en inhoud van die pak
SENTALIS 5 mg:
Geelkleurige, amandelvormige, bikonvekse filmbedekte tablette met 'L 62' aan die een kant gegraveer en glad aan die ander kant.
SENTALIS 20 mg:
Geelkleurige, amandelvormige, bikonvekse filmbedekte tablette met 'L 64' aan die een kant gegraveer en glad aan die ander kant.

Inhoud van die verpakking:
HDPE houer verpakking:
Tablette word verpak in ronde, wit HDPE houer met kinderbestande sluiting met pulp en hitte-seëlvoering.
Verpakkingsgrootte sluit 30's tablette in.
Stulpstrook verpakking:
Tablette word verpak in deursigtige PVC/PVdC-foelie as die vormingsmateriaal en gewone aluminiumfoelie met hitteseëllak as dekmateriaal.
Verpakkingsgroottes sluit in:
SENTALIS 5 mg – Verpakkingsgrootte sluit 10'e, 14's, 28's of 100 tablette in.
SENTALIS 20 mg - Verpakkingsgrootte sluit 2's, 4's, 8's, 10'e of 100 tablette in.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

HOUER VAN DIE REGISTRASIESERTIFIKAAT
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos), Cussonia-rylaan 1,
Bassonia Rock, Uitbr. 12, Alberton, Suid-Afrika.

Hierdie inligtingstuk was hersien in
26 Februarie 2024

Registrasienommer
SENTALIS 5 MG : 49/7.1.5/1147
SENTALIS 20 MG : 49/7.1.5/1148

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

235 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Section 4. Possible side effects revised to include "unknown frequency".

1. Product: SENTALIS 5/20 MG (Tadalafil Tablets 5/20 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: 330 (L) x 235 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM03991503**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40048 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: PM03991502**
15. Revision no: 02	**16. A/W File name: V:\South Africa\Tadalafil\SA Private Market\03\Tadalafil Tablets PIL - PM03991503.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	Vanita Rajool Digitally signed by Vanita Rajool DN: cn=Vanita Rajool, o=Macleods Pharmaceuticals SA (Pty) Ltd., ou=Responsible Pharmacist, email=vanitar@macleodspharma.com, c=ZA Date: 2025.05.26 09:53:22 +02'00'				

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 Release Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM03991501	28/11/22	25/05/23
2) Exclude Professional Information & dimensions change.	PM03991502	02/11/23	13/01/25
3) Section 4. Possible side effects revised to include "unknown frequency".	PM03991503		