Front Side

350 mm

235 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

MAKLITIO 20 MG (film-coated tablets)
Sildenafil citrate equivalent to 20 mg sildenafil active base.
Sugar free.

Read all of this leaflet carefully before you start taking MAKLITIO 20 MG
- 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.
- **MAKLITIO 20 MG** have 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 **MAKLITIO 20 MG** is and what it is used for
2. What you need to know before you take **MAKLITIO 20 MG**
3. How to take **MAKLITIO 20 MG**
4. Possible side effects
5. How to store **MAKLITIO 20 MG**
6. Contents of the pack and other information

1. What MAKLITIO 20 MG is and what it is used for

MAKLITIO 20 MG contains the active ingredient sildenafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors (PDE5). **MAKLITIO 20 MG** is used to treat pulmonary arterial hypertension (high blood pressure in the blood vessels in the lungs). **MAKLITIO 20 MG** brings down blood pressure by widening these vessels.

2. What you need to know before you take MAKLITIO 20 MG

Do not take MAKLITIO 20 MG:
- If you are hypersensitive (allergic) to sildenafil or any of the other ingredients of **MAKLITIO 20 MG** listed in Section 6.
- If you are taking medicines containing nitrates, or nitric oxide donors such as amyl nitrate ("poppers"). These medicines are often given for relief of angina pectoris (or "chest pain"). **MAKLITIO 20 MG** can cause a serious increase in the effects of these medicines. Tell your doctor if you are taking any of these medicines. If you are not certain, ask your doctor or pharmacist.
- If you are taking erythromycin (used to treat certain infections), ketoconazole or itraconazole to treat fungal infections you should not take **MAKLITIO 20 MG.**
- If you are taking ritonavir or saquinavir therapy for the treatment of HIV, you should not take **MAKLITIO 20 MG.**
- If you have a severe liver problem where your liver is not functioning normally.
- If you have severe renal problem, where your kidney is not functioning normally.
- If your blood pressure is below 90/50 mmHg.

If you are not sure whether you should take **MAKLITIO 20 MG**, contact your doctor.

Warnings and precautions
Talk to your doctor or pharmacist before taking **MAKLITIO 20 MG**
Tell your doctor if you have:
- If you have a severe heart problem.
- If you have recently had a stroke or a heart attack, or if you have low blood pressure at rest.
- If you have high blood pressure.
- If you have certain rare inherited eye disease (such as retinitis pigmentosa).
- If you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow), or any disease or deformity of the penis.
- If you currently have a stomach ulcer, a bleeding disorder (such as haemophilia) or problems with nose bleeds.
- If your disease is due to a blocked or narrow vein rather than a blocked or narrow artery.
- If your liver does not work properly.
- If you take medicines for erectile dysfunction.

Special considerations for patients with kidney or liver problems:
You should tell your doctor if you have kidney or liver problems.

If you are not sure whether you should take **MAKLITIO 20 MG**, contact your doctor.
MAKLITIO 20 MG should not be given to children under the age of 18.

Other medicines and MAKLITIO 20 MG
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
It is especially important to inform your doctor if you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **MAKLITIO 20 MG** with these medicines may cause undesirable interactions.
- If you are taking bosentan therapy for pulmonary hypertension ask your doctor or pharmacist for advice before taking **MAKLITIO 20 MG**, as your dose may need to be adjusted.
- Tell your doctor if you are already taking riociguat.
- **MAKLITIO 20 MG** may cause a serious increase in the effects of medicines called nitrates and nitric oxide donors such as amyl nitrate ("poppers"). These medicines are often used for the relief of angina pectoris (or "chest pain"). You should not take **MAKLITIO 20 MG** if you are taking these medicines.
- If you are taking erythromycin, clarithromycin, telithromycin (these are antibiotics used to treat certain bacterial infections), ketoconazole or itraconazole to treat fungal infections you should not take **MAKLITIO 20 MG.**
- If you are taking ritonavir or saquinavir therapy for the treatment of HIV, you should not take **MAKLITIO 20 MG.**
- If you are taking alpha-blocker therapy for the treatment of high blood pressure or prostate problems, ask your doctor or pharmacist for advice before taking **MAKLITIO 20 MG.**

MAKLITIO 20 MG with food and drink:
You should not drink grapefruit juice when you are taking **MAKLITIO 20 MG.**

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking sildenafil.

Pregnancy:
You should not take **MAKLITIO 20 MG** if you are pregnant.

Breastfeeding:
Stop breastfeeding when you start **MAKLITIO 20 MG** treatment. It is not known if the medicine passes into the breast milk.

Driving and using machines
MAKLITIO 20 MG can cause dizziness and effects on vision. You should not drive or operate machinery until you know how treatment with **MAKLITIO 20 MG** affects you.

3. How to take MAKLITIO 20 MG

Do not share medicines prescribed for you with any other person.
Always take **MAKLITIO 20 MG** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
Take **MAKLITIO 20 MG** by mouth. **MAKLITIO 20 MG** can be taken with or without food. Swallow the tablet whole with a glass of water.

The usual dose is:
The recommended dose is 20 mg (one tablet) three times a day (taken 6 to 8 hours apart) swallowed with or without food.
Your doctor will tell you how long your treatment with **MAKLITIO 20 MG** will last.
If you have the impression that the effect of **MAKLITIO 20 MG** is too strong or too weak, talk to your doctor or pharmacist.

If you take more MAKLITIO 20 MG than you should
You will likely have a headache, diarrhoea, pains in your back or hands and legs.
You should not take more tablets than your doctor tells you to.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Take this leaflet and the rest of the remaining **MAKLITIO 20 MG** with you so the doctor will know what you have taken.

If you forget to take MAKLITIO 20 MG :
If you forget to take **MAKLITIO 20 MG**, take a dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take your tablets at the usual times. Do not take a double dose to make up for forgotten tablets.

MAKLITIO 20 MG
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4. Possible side effects

MAKLITIO 20 MG can have side effects.
Not all side effects reported for **MAKLITIO 20 MG** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **MAKLITIO 20 MG** and tell your doctor immediately or go to the casualty department at your nearest hospital.
- Swelling of face, tongue or throat
- Difficulties in swallowing
- Hives and difficulties in breathing
- Severe skin reactions that can include blistering of the skin.

These are all very serious side effects. If you have them, you may have had a serious reaction to **MAKLITIO 20 MG.** You may need urgent medical attention or hospitalization.

If you experience a sudden decrease or loss of vision and hearing, stop taking Sildenafil citrate and contact your doctor immediately.

Tell your doctor promptly about these or any other unusual symptoms. If the symptoms persist or worsen, seek medical attention.

Frequent side effects may include:
- Flu symptoms, skin infection, inflammation in the stomach & small intestine
- Anaemia
- Fluid retention
- Inability to sleep, anxiety
- Headache, migraine, shakes, burning sensations, "pins and needles", numbness
- Visual disturbances, increased eye redness, light-sensitivity, discolouration in the eye, eye irritation
- Spinning sensation
- Flushing
- Nose-bleeds, cough, nasal congestion
- Diarrhoea, acid reflux, piles, stomach cramps
- Night sweats, hair loss, redness of the skin
- Limb pain, muscle pain, back pain
- Enlargement of the breasts
- Fever
- Increase in weight

Less frequent side effects
- Double vision
- Bleeding from the penis, blood in the semen

Frequency unknown
- Low white blood cell count
- Increased thirst, increased acid in the joints (gout), unstable blood sugar levels, excess of watery fluid causing swelling
- Depression, increased sleepiness, abnormal dreams
- Impaired co-ordination, muscle stiffness, nerve pain, shakes, decreased reflexes, numbness, dizziness, fainting
- Dry eyes, sensitivity to light, eye infections, bleeding eyes, increased tearing of the eye, cataract, increased redness in the eye, loss of blood flow to the optic nerve of the eye, blockage of eye vessels, increased pressure in the eye, sensitivity to light, eye strain, blurry vision, irritation of the eye, dry and painful eyes, discolouration in the eye, loss of vision, retinal detachment (which may appear as tiny specks through your field of vision)
- Spinning sensation, ringing in the ears, inability to hear, ear pain
- Irregular and fast heartbeat, chest pain, abnormal ECG reading
- Low blood pressure
- Inability to breath, asthma, increased cough, increased mucus, tightness in the throat, dryness and swelling of the nose, throat infection, chest infection
- Dry mouth, diarrhoea, nausea, vomiting, stomach pain, bleeding gums, bleeding from the rectum, inability to eat, swelling of the food pipe, swelling of the stomach, abnormal liver function tests
- Rash, skin ulcers, redness, itching, peeling of the skin
- Joint and muscle pain, back pain, arthritis, bone pain, pain in the fingers and toes, torn tendons, inflamed joints
- Inability to control the bladder, bladder infection, blood in the urine
- Abnormal ejaculation, increased breast size, swelling of the genitals, inability to orgasm, prolonged erection
- Facial swelling, shock, tiredness, accidental fall, allergic reactions, chest pain, accidental injury

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 **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **MAKLITIO 20 MG.**

5. How to store MAKLITIO 20 MG

Store at or below 25 °C. Protect from light.
Keep the blisters in the carton until required for use.
Keep HDPE containers 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 pack and other information

What MAKLITIO 20 MG contains
The active ingredient in **MAKLITIO 20 MG** is Sildenafil Citrate equivalent to 20 mg active base. Sugar-free.

Other ingredients include:
Croscarmellose sodium, Dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose and film coating containing hypromellose, titanium dioxide and triacetin.

What MAKLITIO 20 MG look like and contents of the pack
White to off white, round shaped, film coated tablets debossed with 'N'Y on one side and plain on the other side.

HDPE container:
Round, white, HDPE container (30 ml) with 28 mm neck finish, containing 90 tablets, closed with white polypropylene child resistant closure with pulp and heat seal liner and packed in a pre-printed unit carton.

Blister pack:
Clear 250 µ PVC/ 60 gsm PVdC as the forming material and silver coloured plain 25µ aluminium foil/ 6-8 gsm HSL as the lidding material, packed in a pre-printed unit carton.
Pack sizes 10s, 28s, 30s and 90s
Not all pack sizes will be marketed.

Holder of Certificate of Registration and Manufacturer
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
30 May 2024

Registration number
MAKLITIO 20 MG: 51/7.1.5/0406

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrse@macleodspharma.com or contact 011 682 1169.

Back Side

350 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

MAKLITIO 20 MG (filmbedekte tablette)
Sildenafilsitraat gelykstaande aan 20 mg sildenafil aktiewe basis.
Suikervry

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy MAKLITIO 20 MG begin gebruik
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het
- **MAKLITIO 20 MG** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

1. Wat **MAKLITIO 20 MG** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **MAKLITIO 20 MG** neem
3. Hoe om **MAKLITIO 20 MG** te neem
4. Moontlike newe-effekte
5. Hoe om **MAKLITIO 20 MG** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat MAKLITIO 20 MG is en waarvoor dit gebruik word

MAKLITIO 20 MG bevat die aktiewe bestanddeel sildenafil, wat behoort aan 'n groep van medisyne genaamd fosfodiësterase tipe 5 inhibeerders (PDE5). **MAKLITIO 20 MG** word gebruik om pulmonêre arteriële hipertensie (hoë bloeddruk in die bloedvate in die longe) te behandel. **MAKLITIO 20 MG** verlaag bloeddruk deur hierdie vate te verbreed.

2. Wat jy behoort te weet voordat jy MAKLITIO 20 MG neem

Moet nie MAKLITIO 20 MG neem nie:
- Indien jy hipersensitief (allergies) is vir sildenafil of enige van die ander bestanddele van **MAKLITIO 20 MG** gelys in Afdeling 6.
- Indien jy medisyne gebruik, wat nitrate bevat, of stikstofoksiedskenkers soos amielnitraat ("poppers"). Hierdie medisyne word dikwels gegee vir verligting van angina pektoris (of "borskaspyn"). **MAKLITIO 20 MG** kan 'n ernstige toename in die effek van hierdie medisyne veroorsaak. Vertel jou dokter as jy enige van hierdie medisyne gebruik. Indien jy nie seker is nie, vra jou dokter of apteker.
- Indien jy eritromisien (wat gebruik word om sekere infeksies te behandel), ketokonasool of itrakonasool neem om swaminfeksies te behandel, moet jy nie **MAKLITIO 20 MG** neem nie.
- Indien jy ritonavir- of sakwinavir terapie vir die behandeling van MIV neem, moet jy nie **MAKLITIO 20 MG** neem nie.
- Indien jy 'n ernstige lewerprobleem het waar jou lewer nie normaal funksioneer nie.
- Indien jy ernstige nier probleme het, waar jou nier nie normaal funksioneer nie.
- Indien jou bloeddruk onder 90/50 mmHg is.

Indien jy nie seker is of jy **MAKLITIO 20 MG** moet neem of nie, kontak jou dokter.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter of apteker voordat jy **MAKLITIO 20 MG** neem
Vertel jou dokter indien jy die volgende het:
- Indien jy ernstige hart probleme het.
- Indien jy onlangs 'n beroerte of 'n hartaanval gehad het, of as jy lae bloeddruk het wanneer jy rus.
- Indien jy hoë bloeddruk het.
- Indien jy sekere seldsame oorgeërfde oogsiekte het (soos retinitis pigmentosa).
- Indien jy sekelselanemie ('n abnormaliteit van rooibloedselle), leukemie (kanker van bloedselle), veelvuldige miëloom (kanker van beenmurg) of enige siekte of misvorming van die penis het.
- Indien jy tans 'n maagseer het, of 'n bloedings versteuring (soos hemofilie) of probleme met neusbloeding het.
- Indien jou siekte as gevolg van 'n verstopte of vernoude aar eerder as 'n verstopte of vernoude slagaar is.
- Indien jou lewer nie behoorlik werk nie.
- Indien jy medisyne neem vir erektiele disfunksie.

Spesiale oorwegings vir pasiënte met nier- of lewer probleme:
Jy moet jou dokter vertel as jy nier- of lewer probleme het.

Indien jy nie seker is of jy **MAKLITIO 20 MG** moet neem, of nie, kontak jou dokter.
MAKLITIO 20 MG moet nie aan kinders onder die ouderdom van 18 gegee word nie.

Ander medisyne en MAKLITIO 20 MG
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Dit is veral belangrik om jou dokter in te lig as jy ander medisyne op 'n gereelde basis gebruik, insluitend komplementêre of tradisionele medisyne, die gebruik van **MAKLITIO 20 MG** saam met hierdie medisyne kan ongewenste interaksies veroorsaak.
- Indien jy bosentaan terapie vir pulmonêre hipertensie neem, vra jou dokter of apteker vir raad voordat jy **MAKLITIO 20 MG** neem, aangesien jou dosis dalk aangepas moet word.
- Vertel hou dokter indien jy alreeds riokiguat neem.
- **MAKLITIO 20 MG** kan 'n ernstige toename in die effek van medisyne, naamlik nitrate en stikstofoksiedskenkers soos amielnitraat ("poppers") veroorsaak. Hierdie medisyne word dikwels gebruik vir die verligting van angina pektoris (of "borskaspyn"). Jy moet nie **MAKLITIO 20 MG** neem as jy hierdie medisyne gebruik nie.
- Indien jy eritromisien, klaritromisien, telitromisien (dit is antibiotika wat gebruik word om sekere bakteriële infeksies te behandel), ketokonasool of itrakonasool neem om swaminfeksies te behandel, moet jy nie **MAKLITIO 20 MG** neem nie.
- Indien jy ritonavir- of sakwinavir terapie vir die behandeling van MIV neem, moet jy nie **MAKLITIO 20 MG** neem nie.
- Indien jy alfa-blokker terapie gebruik vir die behandeling van hoë bloeddruk of prostaat probleme, vra jou dokter of apteker vir raad voordat jy **MAKLITIO 20 MG** neem.

MAKLITIO 20 MG met voedsel en vloeistof:
Jy moet nie pomelosap drink wanneer jy **MAKLITIO 20 MG** neem nie.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, vermoed dat jy dalk swanger is, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy sildenafil neem.

Swangerskap:
Jy moet nie **MAKLITIO 20 MG** neem as jy swanger is nie.

Borsvoeding:
Hou op borsvoed wanneer jy met **MAKLITIO 20 MG** behandeling begin. Dit is nie bekend of die medisyne in die borsmelk oorgaan nie.

Bestuur en gebruik van masjinerie
MAKLITIO 20 MG kan duiseligheid en effekte op visie veroorsaak. Jy moet nie bestuur of masjinerie gebruik totdat jy weet hoe behandeling met **MAKLITIO 20 MG** jou affekteer nie.

3. Hoe om MAKLITIO 20 MG te gebruik

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **MAKLITIO 20 MG** presies soos jou dokter jou beveel het. Bevestig met jou dokter of apteker as jy nie seker is nie.
Neem **MAKLITIO 20 MG** per mond. **MAKLITIO 20 MG** kan met of sonder kos geneem word. Sluk die tablet heel met 'n glas water.

Die gewone dosis is:
Die aanbevole dosis is 20 mg (een tablet) drie keer per dag (geneem 6 tot 8 uur uitmekaar) ingesluk met of sonder kos.
Jou dokter sal jou vertel vir hoe lank jou behandeling met **MAKLITIO 20 MG sal** duur.
Indien jy die indruk het dat die effek van **MAKLITIO 20 MG** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer MAKLITIO 20 MG neem as wat jy behoort te neem
Jy sal waarskynlik 'n hoofpyn, diaree, pyn in jou rug of hande en bene hê.
Jy moet nie meer tablette neem as wat jou dokter vir jou voorskryf nie.

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of giftebeheersentrum.

Neem hierdie inligtingstuk en die res van die oorblywende **MAKLITIO 20 MG** saam met jou, sodat die dokter kan weet wat jy geneem het.

Indien jy vergeet om MAKLITIO 20 MG te neem:
Indien jy vergeet om **MAKLITIO 20 MG** te neem, neem 'n dosis sodra jy daarvan onthou. As dit amper tyd is vir jou volgende dosering, slaan die vergete dosis oor en gaan voort om jou tablette op die gewone tye te neem. Moet nie 'n dubbele dosis neem om op te maak vir vergete tablette nie.

4. Moontlike newe-effekte

MAKLITIO 20 MG kan newe-effekte hê.
Nie al die newe-effekte wat vir **MAKLITIO 20 MG** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verswak of indien jy enige ongewenste effekte ervaar terwyl jy hierdie medisyne neem, kontak asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om **MAKLITIO 20 MG** te neem en sê onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Swelling van die gesig, lippe of keel
- Probleme om te sluk
- Galbulte en probleme met asemhaling
- Ernstige velreaksies wat blase op die vel kan insluit.

Al hierdie newe-effekte is baie ernstig. Indien jy dit ervaar, het jy moontlik 'n ernstige reaksie op **MAKLITIO 20 MG** gehad. Jy mag dringende mediese aandag of hospitalisasie benodig.

Indien jy 'n skielike afname of verlies van sig en gehoor ervaar, hou op om Sildenafilsitraat te neem en kontak onmiddellik jou dokter.

Vertel onmiddellik jou dokter van hierdie of enige ander ongewone simptome. Indien die simptome voortduur of vererger, soek mediese hulp.

Gereelde newe-effekte kan die volgende insluit:
- Griepsimptome, veilinfeksie, ontsteking in die maag & dunderm
- Anemie
- Vog retensie
- Onvermoë om te slaap, angs
- Hoofpyn, migraine, rukkings, brandende sensasies, "speld en naalde", gevoelloosheid
- Visuele versteurings, verhoogde oogrooiheid, ligsensitiwiteit, verkleuring in die oog, oogirritasie
- Draai sensasie
- Gloede
- Neusbloeding, hoes, neusverstopping
- Diaree, suur refluks, aambeie, maagkrampe
- Nagsweet, haarverlies, rooiheid van die vel
- Ledemaatpyn, spierpyn, rugpyn
- Vergroting van die borste
- Koors
- Toename in gewig

Minder gereelde newe-effekte
- Dubbel visie
- Bloeding uit die penis, bloed in die semen

Frekwensie onbekend
- Lae witbloedseltelling
- Verhoogde dors, verhoogde suur in die gewrigte (jig), onstabiele bloedsuikervlakke, oormaat van waterige vloeistof wat swelling veroorsaak
- Depressie, verhoogde slaperigheid, abnormale drome
- Verswakte koördinasie, spierstyfheid, senuwespyn, rukkings, verminderde reflekse, gevoelloosheid, duiseligheid, floute
- Droë oë, sensitiwiteit vir lig, ooginfeksies, bloeiende oë, verhoogde trane van die oog, ketarak, verhoogde rooiheid in die oog, verlies van bloedvloei na die optiese senuwee van die oog, verstopping van oogvate, verhoogde druk in die oog , sensitiwiteit vir lig, spanning in die oë, dowwe visie, irritasie van die oog, droë en pynlike oë, verkleuring in die oog, verlies aan visie, retinale loslating (wat kan lyk soos klein spikkels in jou gesigsveld)
- Draai sensasie, suis in die ore, onvermoë om te hoor, oorpyn
- Onreëlmatige en vinnige hartklop, borskaspyn, abnormale EKG-lesing
- Lae bloeddruk
- Onvermoë om asem te haal, asma, verhoogde hoes, verhoogde slym, toetrek van die keel, droogheid en swelling van die neus, keelinfeksie, borskas infeksie
- Droë mond, diaree, naarheid, braking, maagpyn, bloeiende landvleis, bloeding uit die rektum, onvermoë om te eet, swelling van die slukderm, swelling van die maag, abnormale lewerfunksietoetse
- Uitslag, velsere, rooiheid, jeuk, afskilfering van die vel
- Gewrigs- en spierpyn, rugpyn, artritis, beenpyn, pyn in die vingers en tone, geskeurde senings, ontsteekte gewrigte
- Onvermoë om die blaas te beheer, blaasinfeksie, bloed in die urine
- Abnormale ejakulasie, vergrote borsgrootte, swelling van die geslagsdele, onvermoë om orgasme te kry, langdurige ereksie
- Gesigswelling, skok, moegheid, toevallige val, allergiese reaksies, borskaspyn, toevallige besering

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

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 deur middel van die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **MAKLITIO 20 MG.**

5. Hoe om MAKLITIO 20 MG te bewaar

Bewaar by of benede 25 °C. Beskerm teen lig.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Hou die HDPE houers 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/etiket/karton/bottel nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat MAKLITIO 20 MG bevat
MAKLITIO 20 MG
Die aktiewe bestanddeel in **MAKLITIO 20 MG** is Sildenafilsitraat gelykstaande aan 20 mg sildenafil aktiewe basis.
Suikervry.

Ander bestanddele sluit in:
Natriumkruiskarmellose, dibasiese kalsiumfosfaatdihidraat, hipromellose, magnesiumstearaat, mikrokristallyne sellulose en filmbedekking wat hipromellose, titaandioksied en triasetien bevat.

Hoe MAKLITIO 20 MG lyk en inhoud van die pak
Wit tot naeswit, rond gevormde, filmbedekte tablette met 'N'Y' aan die een kant gegraveer en glad aan die ander kant.
HDPE houer:
Ronde, wit HDPE houer (30 ml) met 28 mm nekafwerking, wat 90 tablette bevat, toegemaak met 'n wit polipropileen sluiting met pulp en hittesëlvoering en verpak in 'n voorafgedrukte eenheidskarton.

Stulpstrook verpakking:
Helder 250 µ PVC/ 60 gsm PVdC as die vormingsmateriaal en silwerkleurige gewone 25µ aluminiumfoelie/ 6-8 gsm HSL as die dekmateriaal, verpak in 'n voorafgedrukte eenheidskarton.
Verpakkingsgroottes 10's, 28's, 30's en 90's
Nie alle verpakkingsgroottes sal bemark word nie.

Houer van die Registrasiesertifikaat en Vervaardiger
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid Afrika

Hierdie inligtingstuk was laas hersien in
30 Mei 2024

Registrasienommer
MAKLITIO 20 MG: 51/7.1.5/0406

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.

235 mm

MASTER COPY

PACKAGING RESEARCH & DEVELOPMENT

MACLEODS

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Update in section 4.0 Possible side effects, Retinal detachment (which may appear as tiny specks through your field of vision) is added in frequency unknown.

1. Product: MAKLITIO 20 MG (Sildenafil Tablets 20 mg)	
2. Country: South Africa (Private Market)	3. Packaging component: Patient Information
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 350 (L) x 235 (W) mm
9. Design / Style: Booklet	10. Item code No.: PM03993603
11. Artwork has been made: Actual Size	12. Pharma code No.: 33918 mini
13. Barcode/NDC No: NA	14. Supersedes item code No: PM03993602
15. Revision No: 02	16. A/W File name:Z:\Sildenafil Tablets\SA Private Market\03\Sildenafil 20 mg Tablets PIL PM03993603.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
31/07/2024	Vanita Rajool	01/08/24	03/08/24	03/08/24	06/8/24

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	PM03993601	01/12/22	04/02/23
2) Exclude Professional Information, Description of tablets & Dimensions change.	PM03993602	22/11/23	01/11/2023
3) Update in section 4.0 Possible side effects, Retinal detachment (which may appear as tiny specks through your field of vision) is added in frequency unknown.	PM03993603		

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