270 mm

MAKDOSIN 4 mg
MAKDOSIN 8 mg
PM04308401

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MAKDOSIN 4 mg
Contains sugar Mannitol (133.35 mg)

MAKDOSIN 8 mg
Contains sugar Mannitol (266.7 mg)

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

1. What MAKDOSIN is and what it is used for

MAKDOSIN belongs to a group of medicines called alpha1A-adrenoreceptor blockers. By blocking these receptors, it causes smooth muscle in these tissues to relax. This makes it easier for you to pass water and relieves your symptoms.

MAKDOSIN is used in male patients to treat the urinary symptoms associated with benign enlargement of the prostate (prostatic hyperplasia), such as:
- Difficulty in starting to pass water,
- a feeling of not completely emptying the bladder, or
- a more frequent need to pass water, even at night.

2. What you need to know before you take MAKDOSIN

Do not take MAKDOSIN:
if you are allergic (hypersensitive) to silodosin or any of the other ingredients of **MAKDOSIN**, listed in section 6.

Warnings and precautions
Take special care with MAKDOSIN
- If you are undergoing eye surgery because of cloudiness of the lens (cataract surgery), it is important that you immediately inform your eye specialist that you are using or have previously used **MAKDOSIN**. This is because some patients treated with this kind of medicine experienced a loss of muscle tone in the iris (the coloured circular part of the eye) during such a surgery. The specialist can take appropriate precautions with respect to medicine and surgical techniques to be used. Ask your doctor whether or not you should postpone or temporarily stop taking **MAKDOSIN** when undergoing cataract surgery.
- If you have ever fainted or felt dizzy when suddenly standing up, please inform your doctor before taking **MAKDOSIN**. Dizziness when standing up and occasionally fainting may occur when taking **MAKDOSIN**, particularly when starting treatment of if you are taking other medicines that lower blood pressure. If this occurs, make sure you sit or lie down straight away until the symptoms have disappeared and inform your doctor as soon as possible (see also section Driving and using machinery).
- If you have severe liver problems, you should not take **MAKDOSIN**, as it was not tested in this condition.
- If you have problems with your kidneys, please ask your doctor for advice.
- If you have moderate kidney problems, your doctor will start **MAKDOSIN** with caution and possibly with a lower dose (see How to take **MAKDOSIN**). If you have severe kidney problems, you should not take **MAKDOSIN**.
- Since a benign enlargement of the prostate and prostate cancer may present the same symptoms, your doctor will check you for prostate cancer before starting treatment with **MAKDOSIN**. **MAKDOSIN** does not treat prostate cancer.
- The treatment with **MAKDOSIN** may lead to an abnormal ejaculation (decrease in the amount of semen released during sex) that may temporarily affect male fertility. This effect disappears after discontinuation of **MAKDOSIN**. Please inform your doctor if you are planning to have children.

Children and adolescents
- **MAKDOSIN** is not recommended for use in patients aged below 18 years since there is no relevant indication for this age group.

Other medicines and MAKDOSIN
Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines).

Tell your doctor in particular, if you take
- medicines which lower blood pressure (in particular, medicines called alpha1-blockers, such as prazosin or doxazosin), as there is the potential risk that the effect of these medicines may be increased whilst taking silodosin.
- antifungal medicines (such as ketoconazole or itraconazole), medicines used for HIV-AIDS (such as ritonavir) or medicines used after transplants to prevent organ rejection (such as cyclosporin) because these medicines can increase the blood concentration of **MAKDOSIN**.
- medicines for epilepsy or rifampicin (a medicine to treat tuberculosis), since the effect of **MAKDOSIN** may be reduced.

Human reproduction
MAKDOSIN is intended for male patients only. Please consult your doctor, pharmacist or other health care professional for advice.

MAKDOSIN with food and drink:
Always take the capsule with food, preferably at the same time every day.

Driving and using machinery
Do not drive or operate machines if you feel faint, dizzy, drowsy or have blurred vision.
MAKDOSIN contains
MAKDOSIN contains mannitol and may have a laxative effect.

3. How to take MAKDOSIN

- Do not share medicines prescribed for you with any other person.
- Always take **MAKDOSIN** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Take **MAKDOSIN** by mouth.

The usual dose is:
One capsule of **MAKDOSIN 8 mg** per day by oral administration.
Do not break or chew the capsule, but swallow it whole, preferably with a glass of water.

Patients with kidney problems
If you have moderate kidney problems, your doctor may prescribe a different dose. For this purpose **MAKDOSIN 4mg** hard capsules are available.

If you take more MAKDOSIN than you should
If you have taken more than one capsule, inform your doctor as soon as possible. If you become dizzy or feel weak, tell your doctor straight away. If your doctor is not available seek help at the nearest hospital or poison control centre

If you forget to take MAKDOSIN
You may take your capsule later the same day if you have forgotten to take it earlier. If it is almost time for the next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten capsule.

If you stop taking MAKDOSIN
If you stop treatment, your symptoms may reappear.

4. POSSIBLE SIDE EFFECTS

MAKDOSIN can have side effects.
Not all side effects reported for **MAKDOSIN** 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 **MAKDOSIN** 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 **MAKDOSIN**. You may need urgent medical attention or hospitalisation.

The most frequent side effect is a decrease in the amount of semen released during sex. This effect disappears after discontinuation of **MAKDOSIN**. Please inform your doctor if you are planning to have children.

Dizziness, including dizziness when standing up, and occasionally fainting, may occur. If you do feel weak or dizzy, make sure you sit or lie down straight away until the symptoms have disappeared. If dizziness when standing up or fainting occurs, please inform your doctor as soon as possible.

MAKDOSIN may cause complications during a cataract surgery (eye surgery because of cloudiness of the lens, see section Take special care with **MAKDOSIN**). It is important that you immediately inform your eye specialist if you are using or have previously used **MAKDOSIN**.

These are all serious side effects. You may need urgent medical attention. Tell your doctor if you notice any of the following:
Frequent side effects
- Abnormal ejaculation (less or no noticeable semen is released during sex.
- Dizziness, including dizziness when standing up, which may lead to collapse
- Runny or blocked nose
- Diarrhoea

Less frequent side effects
- Decreased sexual drive
- Nausea
- Dry mouth
- Difficulties in getting or keeping an erection
- Fainting
- Allergic type reactions including facial swelling, swollen tongue
- Increased heart rate
- Abnormal liver function
- Decrease in blood pressure

Frequency unknown
- Floppy pupil during cataract surgery (see also above, in this section)

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 **MAKDOSIN.**

5. How to store MAKDOSIN

Store at or below 25 °C. Protect from light
Keep the blisters in the carton until required for use.
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 MAKDOSIN contains
MAKDOSIN 4 mg
The active ingredient is Silodosin.
Each capsule contains 4 mg of silodosin.
The other ingredients are pregelatinized starch and sodium lauryl sulphate, magnesium stearate.
The capsule shell is made up of gelatin, titanium dioxide (E171) and sodium lauryl sulphate.
Contains sugar: mannitol (133.35 mg)

MAKDOSIN 8 mg
The active ingredient is Silodosin.
Each capsule contains 8 mg of silodosin.
The other ingredients are pregelatinized starch and sodium lauryl sulphate, magnesium stearate.
The capsule shell is made up of gelatin, titanium dioxide (E171) and sodium lauryl sulphate.
Contains sugar: mannitol (266.7 mg)

What MAKDOSIN looks like and contents of the pack
MAKDOSIN 4 mg:
Opaque white cap/ opaque white body size "3" capsules containing white to off white powder with 'I 87" on body imprinted with gold ink.
MAKDOSIN 8 mg:
Opaque white cap/ opaque white body size "1" capsules containing white to off white powder with 'I 88' on body imprinted with green ink.
HDPE container pack:
Capsules are packed in 60 ml round, white, HDPE container, 33 mm neck finish with 33 mm child resistant closure, white HS 123 white printed liner.
Capsules are packed in 40 ml or 60 ml round, white, HDPE container, 33 – 400 neck finish with 33 mm child resistant closure with pulp and heat seal liner.
Pack size: 30's, 90's
Blister Pack:
Capsules are packed in cold form laminate, 25 µm OPA/45 µm Aluminum foil/60 µm PVC and Plain 25 µm Aluminum foil/6-8 gsm HSL as the lidding material.
Pack size: 5's, 10's, 20's, 30's, 50's, 90's and 100's
Not all pack sizes may 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.

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05 December 2023

Registration number
MAKDOSIN 4 mg : 56/32.2/0319
MAKDOSIN 8 mg : 56/32.2/0320

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

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

MAKDOSIN 4 mg
Bevat suiker: Mannitol (133,35 mg)

MAKDOSIN 8 mg
Bevat suiker: Mannitol (266,7 mg)

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

Wat is in hierdie inligtingstuk

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

1. Wat MAKDOSIN is en waarvoor dit gebruik word

MAKDOSIN behoort aan 'n groep van medisyne genaamd alfa1A-adrenoreseptor blokkeerders. Deur hierdie reseptore te blokkeer, veroorsaak dit gladdespier in hierdie weefsels om te ontspan. Dit maak dit makliker vir jou om water te passeer en jou simptome te verlig.
MAKDOSIN word in manlike pasiënte gebruik om die urinêre simptome wat geassosieer word met goedaardige vergroting van die prostaat (prostatiese hiperplasie) te behandel, soos:
- Probleme om water te begin passeer,
- 'n gevoel dat die blaas nie heeltemal leeggemaak is nie, of
- 'n meer gereelde behoefte om water te passeer, selfs snags.

2. Wat jy behoort te weet voordat jy MAKDOSIN neem

Moet nie MAKDOSIN neem nie:
- indien jy allergies (hipersensitief) vir silodosien of enige van die ander bestanddele, gelys in afdeling 6, van **MAKDOSIN** is.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met MAKDOSIN
- Indien jy 'n oogoperasie ondergaan as gevolg van troebelheid van die lens (katarakchirurgie), is dit belangrik dat jy jou oogspesialis onmiddellik in kennis stel dat jy **MAKDOSIN** gebruik of voorheen gebruik het. Dit is omdat sommige pasiënte wat met hierdie soort medisyne behandel is, tydens so 'n operasie, 'n verlies aan spiertonus in die iris (die gekleurde sirkelvormige deel van die oog) ervaar het. Die spesialis kan toepaslike voorsorgmaatreëls tref ten opsigte van medisyne en chirurgiese tegnieke wat gebruik moet word. Vra jou dokter of jy **MAKDOSIN** moet uitstel of tydelik moet ophou gebruik wanneer jy 'n katarakoperasies ondergaan.
- Indien jy al ooit flou geword het of duiselig gevoel het wanneer jy skielik opstaan, stel asseblief jou dokter in kennis voordat jy **MAKDOSIN** neem. Duiseligheid wanneer jy opstaan en soms floutes, kan voorkom wanneer **MAKDOSIN** geneem word, veral wanneer jy begin met behandeling of as jy ander medisyne gebruik wat bloeddruk verlaag. Wanneer dit gebeur, maak seker dat jy dadelik gaan sit of gaan lê totdat die simptome verdwyn het en stel jou dokter so gou as moontlik in kennis (sien ook afdeling Bestuur en gebruik van masjinerie).
- Indien jy ernstige **lewerprobleme** het, moet jy nie **MAKDOSIN** neem nie, aangesien dit nie in hierdie toestand getoets is nie.
- Indien jy probleme met jou niere het, vra asseblief jou dokter vir advies.
- Indien jy matige nierprobleme het, sal jou dokter **MAKDOSIN** met omsigtigheid en moontlik met 'n laer dosis begin (sien Hoe om **MAKDOSIN** te gebruik). Indien jy ernstige nierprobleme het, moet jy nie **MAKDOSIN** neem nie.
- Aangesien 'n goedaardige vergroting van die prostaat en prostaatkanker dieselfde simptome kan toon, sal jou dokter jou vir prostaatkanker ondersoek, voordat jy met **MAKDOSIN** begin. **MAKDOSIN** behandel nie prostaatkanker nie.
- Die behandeling met **MAKDOSIN** kan lei tot 'n abnormale ejakulasie (afname in die hoeveelheid semen wat tydens seks vrygestel word) wat die vrugbaarheid van mans tydelik kan beïnvloed. Hierdie effek verdwyn nadat **MAKDOSIN** gestaak word. Stel asseblief jou dokter in kennis indien jy beplan om kinders te hê.

Kinders en adolessente
- **MAKDOSIN** word nie aanbeveel vir gebruik in pasiënte jonger as 18 jarige ouderdom nie, aangesien daar geen relevante indikasie vir hierdie ouderdomsgroep is nie.

Ander medisyne en MAKDOSIN
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Vertel jou dokter in die besonder, as jy die volgende neem
- medisyne wat bloeddruk verlaag (veral medisyne genaamd alfa1-blokkeerders, soos prasosien of doksasosien), aangesien daar die potensiële risiko bestaan dat die effek van hierdie medisyne verhoog kan word terwyl silodosien geneem word.
- swambestrydende medisyne (soos ketokonasool of itrakonasool), medisyne wat gebruik word vir MIV-vigs (soos ritonavir) of medisyne wat na oorplantings gebruik word om orgaanverwerping (soos siklosporien) te verhoed, aangesien hierdie medisyne die bloedkonsentrasie van **MAKDOSIN** kan verhoog.
- medisyne vir epilepsie of rifampisien ('n medisyne om tuberkulose te behandel), aangesien die effek van **MAKDOSIN** verminder kan word. .

Menslike voortplanting
MAKDOSIN is slegs bedoel vir manlike pasiënte. Raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Bestuur en gebruik van masjinerie
Moet nie bestuur of masjiene gebruik as jy flou, duiselig of lomerig voel, of dowwe visie het nie.
MAKDOSIN bevat
MAKDOSIN bevat mannitol en kan 'n lakserende effek hê.

3. Hoe om MAKDOSIN te neem

- Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie
- Neem altyd **MAKDOSIN** presies soos jou dokter of apteker jou beveel het. Raadpleeg jou dokter of apteker indien jy onseker is.
- Neem **MAKDOSIN** per mond.

Die gewone dosis is:
Een kapsule **MAKDOSIN 8 mg** per dag deur orale toediening.
Moet nie die kapsule breek of kou nie, maar sluk dit heel, verkieslik met 'n glas water.

Pasiënte met nierprobleme
Indien jy matige nierprobleme het, kan jou dokter 'n ander dosis voorskryf. Vir hierdie doel is **MAKDOSIN 4 mg** harde kapsules beskikbaar.

Indien jy meer MAKDOSIN neem as wat jy behoort te neem
Indien jy meer as een kapsule geneem het, moet jy jou dokter so gou as moontlik in kennis stel. As jy duiselig word of swak voel, kontak onmiddellik jou dokter. Indien jou dokter nie beskikbaar is nie, soek hulp by die naaste hospitaal of gifbeheersentrum

Indien jy vergeet om MAKDOSIN te neem
Jy kan jou kapsule later, dieselfde dag neem, indien jy vergeet het om dit vroeër die dag te neem. Indien dit amper tyd is vir die volgende dosering, slaan die dosis oor wat jy gemis het. Moet nie 'n dubbele dosis neem om vir 'n vergete kapsule op te maak nie.

Indien jy ophou om MAKDOSIN te neem
Indien jy die behandeling staak, kan jou simptome weer terugkom.

4. Moontlike newe-effekte

MAKDOSIN kan newe-effekte hê.
Nie alle newe-effekte wat vir **MAKDOSIN** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid agteruitgaan of jy enige ongewenste effekte ervaar terwyl jy **MAKDOSIN** gebruik, kontak jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om **MAKDOSIN** te neem en sê onmiddellik vir jou dokter 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 sluk of asemhaling kan veroorsaak',
- 'uitslag of gejeuk',
- floutes'

Hierdie is almal baie ernstige newe-effekte. Indien jy dit kry, het jy moontlik 'n ernstige reaksie op **MAKDOSIN** gehad. Jy mag dringende mediese aandag of hospitalisering benodig.

Die mees algemene newe-effek is 'n afname in die hoeveelheid semen wat tydens seks vrygestel word. Hierdie effek verdwyn na die staking van **MAKDOSIN**. Stel asseblief jou dokter in kennis as jy beplan om kinders te hê.

Duiseligheid, insluitend duiseligheid wanneer jy opstaan, en soms floutes, kan voorkom. As jy wel swak of duiselig voel, maak seker dat jy dadelik gaan sit of gaan lê totdat die simptome verdwyn het. Indien duiseligheid wanneer jy opstaan of floutes voorkom, moet jy jou dokter so gou as moontlik in kennis stel.

MAKDOSIN kan komplikasies veroorsaak tydens 'n katarakoperasie (oogoperasie as gevolg van troebelheid van die lens, sien afdeling: Neem spesiale sorg met **MAKDOSIN**). Dit is belangrik dat jy jou oogspesialis onmiddellik in kennis stel as jy **MAKDOSIN** gebruik of voorheen gebruik het.

Hierdie is alles ernstige newe-effekte. Jy mag dringende mediese aandag benodig.
Vertel jou dokter as jy enige van die volgende opmerk:
<u>Gereelde newe-effekte</u>
- Abnormale ejakulasie (minder of geen merkbare semen word tydens seks vrygestel),
- Duiseligheid, insluitend duiseligheid wanneer jy opstaan, wat kan lei tot ineenstorting
- Loopneus of verstopte neus
- Diaree

<u>Minder gereelde newe-effekte</u>
- Verminderde seksuele dryf
- Naarheid
- Droë mond
- Probleme om 'n ereksie te kry of te hou
- Floute
- Allergiese tipe reaksies insluitend gesigswelling, geswelde tong
- Verhoogde harttempo
- Abnormale lewerfunksie
- Afname in bloeddruk

<u>Frekwensie onbekend</u>
- Slap pupil tydens katarakchirurgie (sien ook hierbo, in hierdie afdeling)

Aanmelding van newe-effekte
Indien jy newe-effekte kry praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys is nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies:
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel https://www.sahpra.org.za/Publications/Index/8, aangaande die veiligheid van **MAKDOSIN**.

5. Hoe om MAKDOSIN te bewaar

Bewaar by of benede 25°C. Beskerm teen lig.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Berg in die oorspronklike houer om sodoende teen lig en vog te beskerm.
HOU BUITE BEREIK VAN KINDERS.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat op die stulpe / etiket / karton / bottel aangedui word 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 MAKDOSIN bevat
MAKDOSIN 4 mg
Die aktiewe bestanddeel is Silodosien.
Elke kapsule bevat 4 mg silodosien.
Die ander bestanddele is pregelatiniseerde stysel en natriumlaurielsulfaat, magnesiumstearaat.
Die kapsuledop bestaan uit gelatien, titaandioksied (E171) en natriumlaurielsulfaat.
Bevat suiker: mannitol (133,35 mg)

MAKDOSIN 8 mg
Die aktiewe bestanddeel is Silodosien.
Elke kapsule bevat 8 mg silodosien.
Die ander bestanddele is pregelatiniseerde stysel en natriumlaurielsulfaat, magnesiumstearaat.
Die kapsuledop bestaan uit gelatien, titaandioksied (E171) en natriumlaurielsulfaat.
Bevat suiker: mannitol (266,7 mg)

Hoe MAKDOSIN lyk en inhoud van die pak
MAKDOSIN 4 mg:
Ondeursigtige wit dop/ ondeursigtige wit liggaam, grootte "3" kapsules wat wit tot naaswit poeier bevat met 'I 87' op liggaam ingeprent met goue ink.
MAKDOSIN 8 mg:
Ondeursigtige wit dop/ ondeursigtige wit liggaam, grootte "1" kapsules wat wit tot naaswit poeier bevat met 'I 88' op liggaam ingeprent met groen ink.
HDPE houer pak:
Kapsules word verpak in 60 ml ronde, wit, HDPE-houer, 33 mm nekafwerking met 33 mm kinderbestande sluiting, wit HS 123 wit gedrukte voering.
Kapsules word verpak in 40 ml of 60 ml ronde, wit, HDPE-houer, 33 – 400 nekafwerking met 33 mm kinderbestande sluiting met pulp en hitte seëlvoering.
Verpakkingsgrootte: 30's, 90's
Stulpstrookpak:
Kapsules word verpak in koue vorm laminaat, 25 µm OPA / 45 µm Aluminiumfoelie / 60 µm PVC en Plein 25 µm Aluminiumfoelie / 6-8 gsm HSL as die dekmateriaal.
Verpakkingsgrootte: 5's, 10'e, 20's, 30's, 50's, 90's en 100'e
Nie alle verpakkingsgroottes word noodwendig bemark nie.

7. Houer van die Registrasiesertifikaat en Vervaardiger

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

Hierdie inligtingstuk was laas hersien in
05 Desember 2023

Registrasienommer
MAKDOSIN 4 mg : 56/32.2/0319
MAKDOSIN 8 mg : 56/32.2/0320

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

270 mm

335 mm

MACLEODS

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: MAKDOSIN 4/8 mg (Silodosin Capsules 4/8 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 270(W) mm
9. Design / Style: Booklet type	10. Item code No.: PM04308401
11. Artwork has been made: Actual Size	12. Pharma code No.: 33560 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
15. Revision no: 00	16. A/W File name: Z:\Silodosin\Private Market\01\SILODOSIN CAPSULES 4-8 MG PIL - PM04308401.cdr
Approved By:	17. Location: Daman

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
16/02/24	Vanita Rajool	20/02/24			22/02/24

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	PM04308401		