Front Side

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

SOLVICYD 5 and 10 Film-coated tablets
Solifenacin succinate
Contains sugar: (69,14 mg and 138,28 mg lactose monohydrate, respectively)

Read all of this leaflet carefully before you start taking SOLVICYD
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- **SOLVICYD** 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 **SOLVICYD** is and what it is used for.
2. What you need to know before you take **SOLVICYD**.
3. How to take **SOLVICYD**.
4. Possible side effects.
5. How to store **SOLVICYD**.
6. Contents of the pack and other information.

1. What SOLVICYD is and what it is used for

SOLVICYD contains a medicine called Solifenacin succinate.
The active substance of **SOLVICYD** belongs to the group of medicines called anticholinergics.
SOLVICYD is used to reduce the activity of an overactive bladder. This enables you to wait longer before having to go to the bathroom and increases the amount of urine that can be held by your bladder.

2. What you need to know before you take SOLVICYD

Do not take SOLVICYD:
- If you are hypersensitive (allergic) to solifenacin succinate or any of the ingredients of **SOLVICYD** (listed in **section 6**).
- If you have the inability to pass water or to empty your bladder completely (urinary retention).
- If you suffer from increased pressure in the eyes, with gradual loss of eye sight (glaucoma).
- If you suffer from the muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles.
- If you have a severe stomach or bowel condition (toxic megacolon).
- If you are undergoing kidney dialyses.
- If you have severe liver disease.
- If you suffer from severe kidney disease or moderate liver disease and at the same time being treated with medicines that may decrease the removal of **SOLVICYD** from the body (for example, ketoconazole).
- If you have disorder of the heart known as prolonged QT interval, whether it is inherited or acquired.
- If you are pregnant or breastfeeding.

Warnings and precautions
Tell your doctor before taking **SOLVICYD**:
Take special care with **SOLVICYD**:

- If you have other underlying diseases (for example heart failure or kidney disease) which may also lead to the urge to frequently urinate. Your doctor should address these conditions first before treatment with **SOLVICYD**.
- If you have trouble emptying your bladder (bladder obstruction) or have difficulty in passing urine. Risk of accumulation of urine in the bladder (urinary retention) is much higher.
- If you have obstruction in the digestive system (constipation).
- If you are at risk of your digestive system slowing down (stomach and bowel movements).
- If you suffer from severe kidney disease.
- If you have moderate liver disease.
- If you are taking medicines which decreases the rate of breakdown of **SOLVICYD** by the body for example ketoconazole.
- If you have a stomach tear (hiatus hernia) or heartburn.
- If you have a nervous system disorder (autonomic neuropathy).
- If you have a condition called QT syndrome or *Torsades de pointes*, which are conditions associated with changes in the electrical activity of the heart (ECG), irregular heartbeat, feeling your heartbeat, faster heartbeat.

Skin allergy that results in swelling of the tissue just below the skin (angioedema) with obstruction of the airway has been reported. If this occurs, you should stop taking **SOLVICYD** and inform your doctor immediately.

Potentially life-threatening allergic reactions (anaphylactic reactions) have been reported. If you experience any allergic reaction, you should stop taking **SOLVICYD** and inform your doctor immediately.

SOLVICYD will only reach its complete effect after 4 weeks at the earliest.

Children and adolescents
Safety in children has not been established, therefore **SOLVICYD** is not recommended for children under 18 years.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **SOLVICYD**.

Other medicines and SOLVICYD
Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).
- Amantadine (used as an anti-viral or Parkinson's disease), some anti-histamines, phenothiazine (for psychiatric disorders), and tricyclic antidepressants as they can reduce the effect of **SOLVICYD**.
- Metoclopramide, domperidone and cisapride, which make the digestive system work faster, as **SOLVICYD** can reduce their effect.
- Ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil and diltiazem, which decrease the rate at which **SOLVICYD** is broken down by the body. If you have severe kidney disease you should not take these medicines with **SOLVICYD** (see **section 2**).
- Rifampicin, phenytoin and carbamazepine, as they increase the rate at which **SOLVICYD** is broken down by the body**.**

Taking SOLVICYD with food, drink and alcohol:
SOLVICYD can be taken with or without food.

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 this medicine.
SOLVICYD is contraindicated in pregnancy and during breastfeeding.

Driving and using machines
SOLVICYD may cause blurred vision, sleepiness and a general feeling of tiredness (somnolence and fatigue). If you suffer from these side effects, do not drive or operate machinery, as it may affect these activities.

3. How to take SOLVICYD

Do not share medicines prescribed for you with any other person.
Always take **SOLVICYD** exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.
The usual dose for **SOLVICYD** is 5 mg per day. Your doctor may increase your dose to 10 mg per day if needed.
You should swallow the whole tablet with some liquid. It can be taken with or without food.

If you take more SOLVICYD than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
The most frequent side effects associated with overdose of **SOLVICYD** are headache, dry mouth, dizziness, drowsiness and blurred vision.

If you forget to take SOLVICYD
It is important that you do not miss any doses. If you miss a dose of **SOLVICYD**, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule once daily.
Do not take a double dose to make up for the forgotten individual doses.

If you stop taking SOLVICYD
Do not stop taking **SOLVICYD** unless your doctor tells you to do so. If you have further questions on the use of **SOLVICYD**, ask your doctor or pharmacist.

4. Possible side effects

SOLVICYD can have side effects.
Not all side effects reported for **SOLVICYD** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **SOLVICYD**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking **SOLVICYD** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting
- Yellowing of the skin and eyes, also called jaundice.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Chest pain
- Angina
- Changes in the way your heart beats e.g. if you notice it beating faster
- Difficulty in breathing
- Less urine than is normal for you

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

Tell your doctor if you notice any of the following:
The following side effects have frequently been reported:
- Blurred vision
- Dry mouth, constipation, nausea, heartburn (dyspepsia), stomach pain

The following side effects have been reported less frequently:
- Bladder infection, inflammation of the bladder due to infection (cystitis)
- Sleepiness, impaired sense of taste (dysgeusia)
- Dry eyes
- Dry nasal passages
- Reflux disease (gastro-oesophageal reflux), dry throat, obstruction of the colon, lodging of a large amount of hardened stool in the large intestine (faecal impaction)
- Dry skin
- Difficulty in passing urine
- Tiredness, accumulation of fluid in the lower legs (oedema),
- Hallucinations, confusion,
- Dizziness and headache,
- Vomiting
- Allergic rash, itching of the skin (pruritus), rash, reddening of patches of the skin (erythema multiforme) or hives (urticaria).

The following side effects have been reported with unknown frequency:
- Dilation of the pupils (mydriasis), difficulty in adjusting focus (cycloplegia), painful eyes with bright light (photophobia)
- Reduced secretion of the mucus of the chest
- Flushing of the skin
- Decreased appetite, high levels of blood potassium which can cause abnormal heart rhythm
- Disturbed state of mind characterised by restlessness, illusions and confusion (delirium)
- Increased pressure in the eyes (glaucoma)
- Voice disorder (dysphonia)
- A painful obstruction of the ileum or other part of the intestine, stomach discomfort
- Liver disorder
- Muscular weakness
- Kidney disorder.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
If you get side effects, talk to your doctor or nurse. 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 **SOLVICYD**.

5. How to store SOLVICYD

Store at or below 25 °C (room temperature). Protect from light.
KEEP OUT OF THE REACH OF CHILDREN.
Store in the original package / container.
Keep the blisters in the carton until required for use.
Keep the HDPE containers closed.
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 SOLVICYD contains
The active ingredient is solifenacin succinate.
The other ingredients are:
Lactose monohydrate, pregelatinised starch, magnesium stearate.
5 mg contains ready mix coating material containing hypromellose, titanium dioxide, lactose monohydrate, polyethylene glycol, talc, iron oxide yellow.
10 mg contains ready mix coating material containing hypromellose, titanium dioxide, lactose monohydrate, polyethylene glycol, talc, iron oxide red.

What SOLVICYD looks like and contents of the pack
SOLVICYD 5 mg:
Light yellow colored, round, biconvex, film coated tablets debossed with 'L 22' on one side and plain on other side.
SOLVICYD 10 mg:
Pinkish white colored, round, biconvex, film coated tablets debossed with 'L 27' on one side and plain on other side.

Blister pack:
Tablets are packed in Clear film 250 µ PVC as the forming material and 25 µ Aluminium preprinted foil/ 6-8 gsm heat seal lacquered as the lidding material, packed in a pre-printed carton.
*Pack size include 5's, 10's or 30's (3x10s) tablets.

HDPE pack:
Pack size 30 tablets
Tablets are packed in a 23 ml white round HDPE container with 28-400 mm neck finish which is closed with 28 mm child resistant closure with pulp and heat seal liner and packed in outer carton.
Pack size 90 tablets
Tablets are packed in a 30 ml white round HDPE container with 28-400 mm neck finish which are closed with 28 mm child resistant closure with pulp and heat seal liner and packed in outer carton.
*Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration
MACLEODS PHARMACEUTICALS SA (PTY) LTD
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Alberton, South Africa.

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06 April 2022

Registration numbers
SOLVICYD 5 mg: 49/5.4/0230
SOLVICYD 10 mg: 49/5.4/0231

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

SOLVICYD 5/10 mg
PM03931702

300 mm

335 mm

Back Side

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S3

SOLVICYD 5 en 10 Filmbedekte tablet
Solifenasiensuksinaat
Bevat suiker: (onderskeidelik 69,14 mg en 138,28 mg laktosemonohidraat)

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy SOLVICYD begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorg verskaffer indien jy verdere vrae het
- **SOLVICYD** 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 **SOLVICYD** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **SOLVICYD** neem
3. Hoe om **SOLVICYD** te neem
4. Moontlike newe-effekte
5. Hoe om **SOLVICYD** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat SOLVICYD is en waarvoor dit gebruik word

SOLVICYD bevat 'n medisyne naamlik Solifenasiensuksinaat.
Die aktiewe bestanddeel van **SOLVICYD** behoort aan 'n groep van medisyne naamlik anticholinergiese middels.
SOLVICYD word gebruik om die aktiwiteit van 'n ooraktiewe blaas te verminder. Dit stel jou in staat om langer te wag voordat jy badkamer toe moet gaan, en verhoog die hoeveelheid uriene wat deur jou blaas gehou kan word.

2. Wat jy behoort te weet voordat jy SOLVICYD neem

Moet nie SOLVICYD neem nie:
- Indien jy hipersensitief (allergies) vir solifenasiensuksinaat of enige van die bestanddele van **SOLVICYD** is (gelys in **afdeling 6**).
- Indien jy die onvermoë het om water te passeer of om jou blaas heeltemal leeg te maak (urinêre retensie).
- Indien jy ly aan verhoogde druk in die oë, met geleidelike verlies van sig (gloukoom).
- Indien jy aan die spiersiekte bekend as miastenie gravis ly, wat 'n uiterste swakheid van sekere spiere kan veroorsaak.
- Indien jy 'n ernstige maag- of dermtoestand (toksiese megakolon) het.
- Indien jy nierdialise ondergaan.
- Indien jy ernstige lewersiekte het.
- Indien jy aan ernstige niersiekte of matige lewersiekte ly en terselfdertyd behandel word met medisyne wat die verwydering van **SOLVICYD** uit die liggaam kan verminder (byvoorbeeld ketokonasool).
- Indien jy 'n versteuring van die hart het bekend as verlengde QT-interval, of dit geërf of verkry is.
- Indien jy swanger is of borsvoed.

Waarskuwings en voorsorgmaatreëls
Vertel jou dokter voordat jy **SOLVICYD** neem:
Neem spesiale sorg met **SOLVICYD**:
- Indien jy. ander onderliggende siektes het (byvoorbeeld hartversaking of niersiekte) wat ook kan lei tot die drang om gereeld te urineer. Jou dokter moet hierdie toestande eers aanspreek voor behandeling met **SOLVICYD**.
- Indien jy sukkel om jou blaas te ledig (blaasobstruksie) of sukkel om uriene te passeer. Die risiko van ophoping van uriene in die blaas (urinêre retensie) is baie hoër.
- Indien jy obstruksie in die spysverteringstelsel het (hardlywigheid).
- Indien jy die risiko loop dat jou spysverteringstelsel stadiger word (maag- en derm bewegings).
- Indien jy aan ernstige niersiekte ly.
- Indien jy matige lewersiekte het.
- Indien jy medisyne neem wat die tempo waarteen **SOLVICYD** deur die liggam afgebreek word verminder, byvoorbeeld ketokonasool.
- Indien jy 'n maagskeur (hiatus breuk) of sooibrand het.
- Indien jy 'n senuweestelsel versteuring het (outonome neuropatie).
- Indien jy 'n toestand genaamd QT-sindroom of *Torsades de pointes* het, wat toestande is wat geassosieer word met veranderinge in die elektriese aktiwiteit van die hart (EKG), onreëlmatige hartklop, voel jou hartklop, vinniger hartklop.

Vel allergie wat lei tot swelling van die weefsel net onder die vel (angioëdeem) met obstruksie van die lugweg is aangemeld. As dit gebeur, moet jy ophou om **SOLVICYD** te neem en onmiddellik jou dokter in kennis stel.

Potensiële lewensgevaarlike allergiese reaksies (anafilaktiese reaksies) is aangemeld. Indien jy enige allergiese reaksie ervaar, moet jy ophou om **SOLVICYD** te neem en onmiddellik jou dokter in kennis stel.

SOLVICYD sal eers, op die vroegste, na 4 weke sy volle effek bereik.

Kinders en adolessente
Veiligheid in kinders is nie vasgestel nie, daarom word **SOLVICYD** nie aanbeveel vir kinders onder 18 jaar nie.

Indien jou dokter vir jou gesê het dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy **SOLVICYD** neem.

Ander medisyne en SOLVICYD
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
- Amantadien (gebruik as 'n antivirale of Parkinson se siekte), sommige antihistamiene, fenotiasien (vir psigiatriese versteurings), en trisikliese antidepressante, aangesien dit die effek van **SOLVICYD** kan verminder.
- Metoklopramied, domperidoon en sisapried, wat die spysverteringstelsel vinniger laat werk, aangesien **SOLVICYD** hul effek kan verminder.
- Ketokonasool, ritonavir, nelfinavir, itrakonasool, verapamil en diltiasem, wat die tempo waarteen **SOLVICYD** deur die liggaam afgebreek word, verlaag. As jy ernstige niersiekte het, moet jy nie hierdie medisyne saam met **SOLVICYD** neem nie (sien **afdeling 2**).
- Rifampisien, fenitoïen en karbamasepien, aangesien dit die tempo waarteen **SOLVICYD** deur die liggaam afgebreek word, verhoog.

Neem SOLVICYD met voedsel, vloeistof en alkohol:
SOLVICYD kan met of sonder kos geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, vermoed dat jy moontlik swanger is, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne neem.
SOLVICYD is teenaangedui in swangerskap en gedurende borsvoeding.

Bestuur en gebruik van masjinerie
SOLVICYD kan dowwe visie, slaperigheid en 'n algemene gevoel van moegheid (somnolensie en vermoeidheid) veroorsaak. Indien jy aan hierdie newe-effekte ly, moet nie bestuur of masjinerie hanteer nie, aangesien dit hierdie aktiwiteite kan beïnvloed.

3. Hoe om SOLVICYD te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie
Neem altyd **SOLVICYD** presies soos jou dokter of apteker vir jou gesê het. Vra vir jou dokter of apteker indien jy nie seker is nie.
Die gewone dosis vir **SOLVICYD** is 5 mg per dag. Jou dokter kan jou dosis verhoog tot 10 mg per dag indien nodig.
Jy moet die hele tablet met 'n bietjie vloeistof sluk. Dit kan met of sonder kos geneem word.

Indien jy meer SOLVICYD 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.
Die mees algemene newe-effekte wat met oordosis van **SOLVICYD** geassosieer word, is hoofpyn, droë mond, duiseligheid, lomerigheid en dowwe visie.

Indien jy vergeet om SOLVICYD te neem
Dit is belangrik dat jy geen dosisse mis nie. Indien jy 'n dosis van **SOLVICYD** oorslaan, neem dit so gou as wat jy daarvan onthou. As dit amper tyd is vir jou volgende dosis, slaan die vergete dosis oor en gaan terug na jou gewone doseringskedule van een keer per dag.
Moet nie 'n dubbele dosis neem om vir die vergete individuele dosisse op te maak nie

Indien jy ophou om SOLVICYD te neem
Moet nie ophou om **SOLVICYD** te neem nie, tensy jou dokter jou beveel om dit te doen. Indien jy verdere vrae het oor die gebruik van **SOLVICYD**, vra jou dokter of apteker.

4. Moontlike newe-effekte

SOLVICYD kan newe-effekte hê.
Nie al die newe-effekte wat vir **SOLVICYD** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige ongunstige effekte ondervind terwyl jy **SOLVICYD** ontvang, kontak asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om **SOLVICYD** te neem en sê onmiddellik vir jou dokter of gaan na die ongevalle afdeling by jou naaste hospitaal:
- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal.
- Uitslag of jeuk
- Floute
- Vergeling van die vel en oë, ook genoem geelsug.

Hierdie is alles baie ernstige newe-effekte. As jy dit het, het jy moontlik 'n ernstige allergiese reaksie op **SOLVICYD** gehad. Jy benodig dalk dringende mediese aandag of hospitalisasie.
- Borskaspyn
- Angina
- Veranderinge in die manier hoe jou hart klop bv. as jy agterkom dit klop vinniger
- Probleme om asem te haal
- Minder uriene as wat vir jou normaal is

Dit is alles ernstige newe-effekte. Jy het moontlik mediese hulp nodig.

Vertel jou dokter as jy enige van die volgende opmerk:
Die volgende newe-effekte is gereeld aangemeld:
- Dowwe visie
- Droë mond, hardlywigheid, naarheid, sooibrand (dispepsie), maagpyn

Die volgende newe-effekte is minder algemeen aangemeld:
- Blaasinfeksie, ontsteking van die blaas as gevolg van infeksie (sistitis)
- Slaperigheid, ingekorte smaak sensasie (disgeusie)
- Droë oë
- Droë neusgange
- Refluks siekte (gastro-esofageale refluks), droë keel, obstruksie van die kolon, vassit van 'n groot hoeveelheid verharde stoelgang in die dikderm (fekale impaksie)
- Droë vel
- Probleme om uriene te passeer
- Moegheid, ophoping van vog in die onderbene (edeem),
- Hallusinasies, verwarring,
- Duiseligheid en hoofpyn,
- Braking
- Allergiese uitslag, jeuk van die vel (pruritus), uitslag, rooi word van kolle van die vel (veelvuldige eriteem) of galbulte (urtikarie).

Die volgende newe-effekte is met onbekende frekwensie aangemeld:
- Verwyding van die pupille (midriase), probleme om fokus aan te pas (sikloplegie), pynlike oë met helder lig (fotofobie)
- Verminderde afskeiding van die mukus van die bors
- Gloede van die vel
- Verminderde eetlus, hoë bloedkaliumvlakke wat abnormale hartritme kan veroorsaak
- Versteurde gemoedstoestand gekenmerk deur rusteloosheid, illusies en verwarring (delirium)
- Verhoogde druk in die oë (gloukoom)
- Heesheid (disfonie)
- 'n Pynlike obstruksie van die ileum of ander deel van die ingewande, maagongemak
- Lewerversteuring
- Spierswakheid
- Niersteuring.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis. Indien jy newe-effekte kry, praat met jou dokter of verpleegkundige. 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 **SOLVICYD**.

5. Hoe om SOLVICYD te bewaar

Bewaar by of benede 25°C (kamertemperatuur). Beskerm teen lig.
HOU BUITE DIE BEREIK VAN KINDERS
Stoor in die oorspronklike verpakking/houer.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Hou die HDPE houers dig toe.
Moet nie in die badkamer bêre nie
Moet nie na die vervaldatum wat aangebring is op die stulpstrook/etiket/karton/bottel 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 SOLVICYD bevat
Die aktiewe bestanddeel is solifenasiensuksinaat.
Die ander bestanddele is:
Laktosemonohidraat, vooraf gegelatineerde stysel, magnesiumstearaat.
5 mg bevat klaargemengde deklaagmateriaal wat hipromellose, titaandioksied, laktosemonohidraat, poliëtileenglikol, talk, geel ysteroksied bevat.
10 mg bevat klaargemengde deklaagmateriaal wat hipromellose, titaandioksied, laktosemonohidraat, poliëtileenglikol, talk, rooi ysteroksied bevat.

Hoe SOLVICYD lyk en inhoud van die pak
SOLVICYD 5 mg:
Liggeel gekleurde, ronde, bikonvekse, filmbedekte tablette gedruk met 'L 22' aan die een kant en glad aan die ander kant.
SOLVICYD 10 mg:
Pienkerige wit gekleurde, ronde, bikonvekse, filmbedekte tablette gedruk met 'L 27' aan die een kant en glad aan die ander kant.
Nie alle verpakkings en verpakkingsgroottes word noodwendig bemark nie.

Stulpstrook verpakking:
Tablette word verpak in deursigtige film 250 µ PVC as die vormingsmateriaal en 25 µ Aluminium voorafgedrukte foelie/ 6-8 gsm hitteseëllak as die dekmateriaal, verpak in 'n voorafgedrukte karton.
*Verpakkingsgrootte sluit 5'e, 10'e of 30's (3x10'e) tablette in.

HDPE verpakking:
Verpakkingsgrootte 30 tablette
Tablette word verpak in 'n 23 ml wit, ronde HDPE houer met 28-400 mm nekafwerking wat toegemaak is met 28 mm kinderbestande sluiting met pulp en hitteseëlvoering en in buitenste karton verpak.
Verpakkingsgrootte 90 tablette
Tablette word verpak in 'n 30 ml wit ronde HDPE houer met 28-400 mm nekafwerking wat toegemaak is met 28 mm kinderbestande sluiting met pulp en hitteseëlvoering en in buitenste karton verpak.
*Nie alle verpakkings en 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 laas hersien in
06 April 2022

Registrasienommer
SOLVICYD 5 mg: 49/5.4/0230
SOLVICYD 10 mg: 49/5.4/0231

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodssaproducts.co.za of e-pos safety@macleodspharma.com of kontak 011 682 1169.

300 mm

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Exclude Professional Information and dimension change.

1. Product: SOLVICYD 5/10 mg (Solifenacin Succinate 5 mg/10 mg film-coated Tablets)					
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 300 (W) mm**		
9. Design / Style: Booklet type			**10. Item code No.: PM03931702**		
11. Artwork has been made: Actual Size			**12. Pharma code No.: 33103 mini**		
13. Barcode/NDC no: NA			**14. Supersedes Item code No: PM03931701**		
15. Revision no: 01			**16. A/W File name:X:\Solifenacin Succinate\SA Private market\01\Solifenacin Tablets PI & PIL - PM03931702.cdr**		
Approved By:			**17. Location: Baddi**		
PRD	**M.A. HOLDER**	**MEDICAL/RAD**	**QC**	**PRODN**	**QA**
	15/09/2025				

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.

Format No: FRM/SOP/CO/CQA/021/03-003

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM03931701	19/10/22	11/11/22
2) Exclude Professional Information and dimension change.	PM03931702		