SILBECOR

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

SILBECOR 10 mg/1 g of cream
Silver sulfadiazine

Read all of this leaflet carefully before you start using SILBECOR
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist nurse or other healthcare provider.
- SILBECOR cream 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 SILBECOR is and what it is used for

SILBECOR is used as a topical wound dressing for the prevention and treatment of infections in wounds and burns. SILBECOR can also be used in the treatment of leg ulcers and pressure sores.

2. What you need to know before you use SILBECOR

Do not use SILBECOR:
- If you are hypersensitive (allergic) to silver sulfadiazine, sulphonamides (antibiotics used to treat bacterial infection and some fungal infections), or any other ingredients of SILBECOR (listed in section 6).
- If you are allergic to peanuts or soya. SILBECOR contains arachis oil (peanut oil).
- If you have liver or kidney problems.
- If you have a rare metabolic disorder which leads to difficulty making a chemical called haem – a constituent of many important proteins in the body (porphyria).
- If you are pregnant of breastfeeding your baby.
- If the patient is a premature infant or infant during the first months of life.

Warnings and precautions

Take special care with SILBECOR:
- SILBECOR is for external use only.
- If you are sensitive (allergic) to sulphonamides (antibiotics used to treat bacterial infections and some fungal infections), furosemide, thiazide diuretics (sometimes called "water pills"), sulphonylureas (a group of medicines used to treat type 2 diabetes) or carbonic anhydrase inhibitors (medicine used in the management and treatment of high pressure in the eye, a build-up of pressure around the brain, altitude sickness, congestive heart failure and epilepsy/ seizures) as you may be sensitive to SILBECOR.
- If you have a deficiency of the enzyme known as glucose-6-phosphate dehydrogenase which may cause paleness, extreme tiredness or dizziness, fast heartbeat, fast breathing or shortness of breath, yellowing of the eyes and skin and an enlarged spleen.
- When a fall in white blood cell count is demonstrated (high fever, chills and sweating), your blood count should be monitored to ensure that it returns to normal within a few days.
- When SILBECOR is applied to a large area and when the lesion(s) is/ are deep as appreciable amounts of SILBECOR may be absorbed and cause systemic side effects such as blue-grey discolouration of the skin and damage to nerve cells, nerve fibres and nerve coverings.
- As there is a risk of crystallisation in the urine. It may be reduced by the intake of adequate fluids and normalisation of the acid base.
- When exposed to sunlight as local skin sensitivity to SILBECOR may occur.
- When a rash appears, treatment should be discontinued because of the danger of a severe allergic reaction called Stevens-Johnson syndrome (characterised by severe blisters and bleeding in the lips, eyes, mouth, nose and genitals).
- When you are an elderly patient as you may be particularly prone to adverse reactions.
- If you have acquired immunodeficiency syndrome (AIDS) as you may be particularly prone to adverse reactions.

Other medicines and SILBECOR:

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

SILBECOR may enhance the effects of the following medicines:
- Oral antidiabetic medicines.
- Blood thinning tablets (warfarin).
- Methotrexate used in the treatment of cancer and autoimmune diseases (conditions in which the body's immune system attacks its own healthy cells).
- Antiepileptic medicine called phenytoin.

SILBECOR can increase the antidiabetic effect of sulphonylurea medicines used in the treatment of diabetes.
Concurrent use of cimetidine (medicine used to lower stomach acid) and SILBECOR, may contribute to a decrease in white blood cells and the development of side effects.
SILBECOR may affect the working of enzymatic debriding agents (certain medicine enzymes, prescribed to remove necrotic or dead tissue).

Pregnancy and breastfeeding

SILBECOR should not be used during pregnancy or while you are breastfeeding.
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 healthcare provider for advice before using SILBECOR.

Driving and using machines

SILBECOR should have no or limited effect on your ability to drive a vehicle or operate machinery but the effect on you as individual should be known before you drive a vehicle or operate machines.

SILBECOR contains cetyl alcohol and propylene glycol

SILBECOR contains cetyl alcohol which may cause local skin reactions (e.g. skin rash) and 100 mg/g propylene glycol which may cause skin irritation.

3. How to use SILBECOR

Do not share medicines prescribed for you with any other person. Always use SILBECOR exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Do not swallow SILBECOR cream.

SILBECOR should be applied daily in a layer approximately 3 - 5 mm thick with a sterile gloved hand or spatula. The wound may be dressed or left open. One container of SILBECOR should be reserved for one patient and any remaining cream should be discarded on completion of treatment.
There are some bacteria which may develop resistance to silver sulfadiazine and you are advised to consult with your doctor, if you have been using SILBECOR without any noticeable result in the healing of your wound/ulcer.
Your doctor will tell you how long your treatment with SILBECOR will last.

If you use more SILBECOR than you should

If an allergic reaction occurs discontinue use, treatment is symptomatic and supportive.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use SILBECOR

If you miss an application of SILBECOR cream, apply the dose as soon as you remember, and continue with the normal dosing schedule.

4. Possible side effects

SILBECOR can have side effects.
Not all side effects reported for SILBECOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using SILBECOR, please consult your doctor, pharmacist of other health care provider for advice.

If any of the following happens, stop using SILBECOR 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SILBECOR. 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:

Frequent side effects:
- a drop in blood sugar levels,
- kidney disorders (lower back pain, passage of blood in the urine, production of an abnormally small amount of urine, failure of the kidneys to pass urine),
- crystallisation in urine (therefore, adequate fluid intake and normalisation of the acid base balance are important),
- leucopenia, which is when you have a low level of white blood cells and is characterised by frequent infections.

Less frequent side effects:
- any symptoms that may indicate a problem with the cells in your blood, the problems being, an acute deficiency of certain blood cells, failure of blood cell production, a decrease in the number of blood platelets, reduction in the number of white blood cells, change in blood clotting time or a blood cell condition called eosinophilia (an increase in some white blood cells). The symptoms may include rash, itching, asthma, fatigue, fever, sores in the mouth or throat, shortness of breath, pale skin, easy bruising, nosebleeds, bleeding gums, prolonged bleeding from cuts,
- kidney failure,
- local pain and irritation, fungal infection of the wound.

Side effects with unknown frequency:
- Stevens-Johnson syndrome, the symptoms may include a painful red or purplish rash that spreads and blisters, and peeling of the skin,
- toxic epidermal necrolysis (severe peeling and necrosis of the skin),
- yellowing of the skin and eyes, also called jaundice.
- fits or seizures (convulsions),
- thyroid problems (hypothyroidism),
- inflammation of the lining of the brain characterised by fever, chills, headache, loss of appetite, nausea, vomiting and fatigue (aseptic meningitis (aseptic meningitis),
- benign intracranial hypertension (high pressure in spaces surrounding the brain and spinal cord),
- systemic lupus erythematosus (characterised by fatigue, joint pain, rash and fever),
- inflammation of the pancreas (pancreatitis),
- liver necrosis,
- pulmonary eosinophilia, fibrosing alveolitis diseases causing for instance symptoms similar to asthma,
- narrowing or blockage of blood vessels,
- heart problems (adverse effect because of possible allergic reaction).

Tell your doctor if you notice any of the following:

Frequent side effects:
- nausea (feeling sick), vomiting (being sick), loss of appetite (anorexia), diarrhoea
- rash at site of application,
- fever, application site burning,
- skin sensitivity to sunlight,
- painful bumps under skin.

Less frequent side effects:
- purplish grey discoloration of the skin.

Side effects with unknown frequency:
- dizziness,
- headache,
- fatigue,
- drowsiness,
- trouble falling asleep,
- depression,
- weakness, numbness and pain in the hands and feet,
- vision disturbances or loss of vision,
- spinning sensation (vertigo),
- feeling disconnected from reality (psychoses),
- impaired balance or coordination (ataxia).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the **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 SILBECOR.

5. How to store SILBECOR
- Store all medicines out of reach of children.
- Store at or below 25 °C. Protect from light.
- 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 SILBECOR contains:

Each gram contains 10 mg silver sulfadiazine.
The other ingredients are arachis oil (hydrogenated), cetyl alcohol, polysorbate 60, purified water, propylene glycol, methyl paraben, propyl hydroxybenzoate.
Preservatives: methyl hydroxybenzoate (0,15 % m/m) and propyl hydroxybenzoate (0,05 % m/m).

What SILBECOR looks like and contents of the pack

SILBECOR is an odourless, white homogenous cream.

SILBECOR will be packed in either of the following packaging material:

1. 250 g plastic jar
Black blow moulded HDPE jar with black polypropylene cap.
2. 500 g plastic jar
Black blow moulded HDPE jar with black polypropylene cap.
Not all pack sizes may be marketed.

Holder of certificate of registration

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This leaflet was last revised

01 December 2021

Registration number

29/14.2/0338

Botswana: Silbecor 250 g: Reg. No. BOT1803410A Silbecor 500 g: Reg. No. BOT1803410B		S3 S3	
Namibia: Reg. No. 12/14.2/0153	NS2	Zimbabwe: Reg. No. 98/14.1.2/3422	PP10

SILBECOR

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS

S4

SILBECOR 10 mg/1 g room
Silwersulfadiasien

Lees hierdie hele pamflet noukeurig deur voordat jy begin om SILBECOR te gebruik
- Hou hierdie pamflet. Jy mag dit dalk weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- SILBECOR room is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander persone deel nie. Dit kan hulle skade aandoen, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet

1. Wat SILBECOR is en waarvoor dit gebruik word

SILBECOR word gebruik as 'n topikale wondbedekking vir die voorkoming en behandeling van infeksies in wonde en brandwonde. SILBECOR kan ook gebruik word in die behandeling van beensere (ulkusse) en druksere.

2. Wat jy moet weet voordat jy SILBECOR gebruik

Moenie SILBECOR gebruik nie:
- Indien jy hipersensitief (allergies) is vir sulfadiasien, sulfanomiede (antibiotika wat gebruik word om bakteriële infeksie en sommige swaminfeksies te behandel), of enige ander bestanddele van SILBECOR (gelys in afdeling 6).
- Indien jy allergies is vir grondbone of soja. SILBECOR bevat arachisolie (grondboontjie-olie).
- Indien jy lewer- of nierprobleme het.
- Indien jy 'n seldsame metaboliese afwyking het wat lei tot die maak van 'n chemikalieë genaamd heem – 'n bestanddeel van baie belangrike proteïene in die liggaam (porfirie).
- Indien jy swanger is of jou baba borsvoed.
- Indien die pasiënt 'n premature baba of 'n baba is gedurende die eerste maande van lewe.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met SILBECOR:
- SILBECOR is vir eksterne gebruik alleenlik.
- Indien jy sensitief (allergies) is vir sulfonamiede (antibiotika wat gebruik word om bakteriële infeksies en sommige swaminfeksies te behandel), furosemied, tiasied diuretika (soms genoem "watertablette"), sulfonielureas ('n groep medisyne wat gebruik word om tipe 2-diabetes te behandel) of koolsuuranhidrase-inhibeerders (medisyne wat gebruik word in die hantering en behandeling van hoë druk in die oog, 'n opbou van druk rondom die brein, hoogtesiekte, kongestiewe hartversaking en epilepsie/ aanvalle) aangesien jy sensitief kan wees vir SILBECOR.
- Indien jy 'n tekort aan die ensiem, bekend as glukose-6-fosfaatdehidrogenase het wat bleekheid, uiterste moegheid of duiseligheid, vinnige hartklop, vinnige asemhaling of kortasem, vergeling van die oë en vel en 'n vergrote milt kan veroorsaak.
- Wanneer 'n daling in witbloedselle voorkom (hoë koors, kouekoors en sweet), moet jou bloedtelling gemonitor word om te verseker dat dit binne 'n paar dae na normaal terugkeer
- Wanneer SILBECOR aan 'n groot area toegedien word en wanneer die letsel(s) diep is, kan aansienlike hoeveelhede SILBECOR geabsorbeer word en sistemiese newe-effekte veroorsaak soos blougrys verkleuring van die vel en skade aan senuweeselle, senuweevesels en senuweebedekkings.
- Aangesien daar 'n risiko van kristallisasie in die uriene is, kan die risiko verminder word deur die inname van voldoende vloeistowwe en normalisering van die suurbasis
- Wanneer dit aan sonlig blootgestel word, aangesien plaaslike velsensitiwiteit vir SILBECOR kan voorkom.
- Wanneer 'n uitslag voorkom moet behandeling gestaak word weens die gevaar van 'n ernstige allergiese reaksie genaamd Stevens-Johnson-sindroom (gekenmerk deur erge blase en bloeding op die lippe, oë, mond, neus en geslagsdele).
- Wanneer jy 'n bejaarde pasiënt is, aangesien jy dalk veral geneig is tot nadelige reaksies.
- As jy immuniteitsgebreksindroom (VIGS) opgedoen het, aangesien jy dalk veral geneig is tot nadelige reaksies.

Ander medisyne en SILBECOR:
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).

SILBECOR kan die uitwerking van die volgende medisyne versterk:
- Orale antidiabetiese medisyne.
- Bloedverdunningstablette (warfarien).
- Metotreksaat wat gebruik word in die behandeling van kanker en outo-immuun siektes (toestande waarin die liggaam se immuunstelsel sy eie gesonde selle aanval).
- Anti-epileptiese medisyne genoem fenitoïen.

SILBECOR kan die antidiabetiese effek van sulfonielureammedisyne wat in die behandeling van diabetes gebruik word, verhoog. Gelyktydige gebruik van simetidien (medisyne wat gebruik word om maagsuur te verlaag) en SILBECOR kan bydra tot 'n afname in witbloedselle en die ontwikkeling van newe-effekte.
SILBECOR kan die werking van ensiematiese debrideringsmiddels (sekere medisyne-ensieme, voorgeskryf om nekrotiese of dooie weefsel te verwyder) beïnvloed.

Swangerskap en borsvoeding
SILBECOR moet nie gebruik word gedurende swangerskap of terwyl jy borsvoed nie.
Indien jy swanger is of borsvoed, dink dat jy dalk mag swanger wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy SILBECOR gebruik.

Bestuur en gebruik van masjiene
SILBECOR behoort geen of beperkte uitwerking te hê op jou vermoë om 'n voertuig te bestuur of masjinerie te bestuur nie, maar die effek op jou as individu moet bekend wees voordat jy 'n voertuig bestuur of masjiene gebruik.

SILBECOR bevat setielalkohol en propileenglikol
SILBECOR bevat setielalkohol wat plaaslike velreaksies kan veroorsaak (bv. veluitslag) en 100 mg/g propileenglikol wat velirritasie kan veroorsaak.

3. Hoe om SILBECOR te gebruik

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Gebruik altyd SILBECOR presies soos jou dokter of apteker vir jou vertel het. Jy moet seker maak met jou dokter of apteker indien jy nie seker is nie.

Moenie SILBECOR sluk nie
SILBECOR moet daagliks toegedien word in 'n lagie van ongeveer 3 - 5 mm dik met 'n steriele handskoen of spatel. Die wond kan geklee wees of oopgelaat word. Een houer SILBECOR moet vir een pasiënt gereserveer word en enige oorblywende room moet weggegooi word na voltooiing van behandeling.
Daar is sommige bakterieë wat weerstand teen silwersulfadiasien kan ontwikkel en jy word aangeraai om met jou dokter te konsulteer as jy SILBECOR gebruik het sonder enige merkbare resultaat in die genesing van jou wond/ ulkus.
Jou dokter sal jou vertel hoe lank jou behandeling met SILBECOR sal duur.

Indien jy meer SILBECOR gebruik as wat jy moet
Indien 'n allergiese reaksie voorkom, staak die gebruik. Behandeling is simptomaties en ondersteunend.
In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om SILBECOR te gebruik
Indien jy 'n aanwending van SILBECOR room mis, wend die dosis aan so gou as wat jy daarvan onthou en gaan voort met die normale doseringskedule.

4. Moontlike newe-effekte

SILBECOR kan newe-effekte hê.
Nie al die newe-effekte wat vir SILBECOR aangemeld is word in hierdie pamflet bevat nie. Indien jou algemene gesondheid sou versleg of indien jy enige ongewensde effekte ervaar terwyl jy SILBECOR gebruik, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om SILBECOR te gebruik en vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat moeilike sluk of moeilike asemhaling kan veroorsaak,
- veluitslag of jeuk,
- floute.

Hierdie is almal baie ernstige newe-effekte. Indien jy hulle het mag jy dalk 'n ernstige reaksie op SILBECOR gehad het. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
Gereelde newe-effekte:
- 'n daling in bloedsuikervlakke,
- Nierversteurings (lae rugpyn, die teenwoordigheid van bloed in die uriene, produksie van 'n abnormale klein hoeveelheid uriene, mislukking van die nier om uriene deur te gee),
- kristallisasie in uriene (dus is voldoende vloeistofinname en normalisering van die suurbasisbalans belangrik),
- leukopenie, wat is wanneer jy 'n lae vlak van witbloedselle het en dit word gekenmerk deur gereelde infeksies.

Minder gereelde newe-effekte:
- enige simptome wat kan dui op 'n probleem met die selle in jou bloed, die probleme is, 'n akute tekort aan sekere bloedselle, mislukking van bloedselproduksie, 'n afname in die aantal bloedplaatjies, vermindering in die aantal witbloedselle, verandering in bloedstollingstyd of 'n bloedseltoestand genaamd eosinofilie ('n toename in sommige witbloedselle). Die simptome kan insluit uitslag, jeuk, asma, moegheid, koors, sere in die mond of keel, kortasem, bleek vel, maklike kneusing, neusbloeding, bloeiende tandvleis, langdurige bloeding van snye,
- nierversaking,
- lokale pyn en irritasie, swaminfeksie van die wond.

Newe-effekte met onbekende frekwensie:
- Stevens Johnson se sindroom, die simptome kan 'n pynlike rooi of perserige uitslag insluit wat versprei en blase, en afskilfering van die vel,
- toksiese epidermale nekrolise (ernstige afskilfering en nekrose van die vel),
- vergeling van die vel en oë, ook genoem geelsug,
- stuipe of aanvalle (konvulsies),
- skildklierprobleme (hipotireose),
- ontsteking van die voering van die brein wat gekenmerk word deur koors, kouekoors, hoofpyn, verlies aan eetlus, naarheid, braking en moegheid (aseptiese meningitis),
- benigne intrakraniale hipertensie (hoë druk in spasies rondom die brein en rugmurg),
- sistemiese lupus erythematosus (gekenmerk deur moegheid, gewrigspyn, uitslag en koors),
- inflammasie van die pankreas (pankreatitis),
- livernekrose,
- pulmonêre eosinofilie, fibroserende alveolitis siektes wat byvoorbeeld simptome soortgelyk aan asma veroorsaak,
- vernouing of blokkasie van bloedvate,
- hartprobleme (nadelige effek as gevolg van moontlike allergiese reaksie).

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereelde newe-effekte:
- naarheid (siek gevoel), braking (siek wees), verlies aan eetlus (anoreksie), diarree
- uitslag op die plek van toediening,
- koors, brand van toedieningsplek,
- velsensitiwiteit vir sonlig,
- pynlike knoppe/ bulte onder die vel.

Minder gereelde newe-effekte:
- persgrys verkleuring van die vel.

Newe-effekte met onbekende frekwensie:
- duiseligheid,
- hoofpyn,
- moegheid,
- lomerigheid,
- probleme om aan die slaap te raak,
- depressie,
- swakheid, gevoelloosheid en pyn in die hande en voete,
- visieversteurings of verlies aan visie,
- spinnende sensasie (vertigo),
- voel ontkoppel van die werklikheid (psigose),
- versteurde balans of koördinasie (ataksie).

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

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA aanmeld deur die vorm **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 oor die veiligheid van SILBECOR te verskaf.

5. Hoe om SILBECOR te bewaar

- Bewaar alle medisyne buite bereik van kinders.
- Bewaar teen of benede 25 °C. Beskerm teen lig.
- Gee alle ongebruikte medisyne terug aan jou apteker.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat SILBECOR bevat:
Elke gram bevat 10 mg silwersulfadiasien.
Die ander bestanddele is arachisolie (gehidrogeneerd), setielalkohol, polisorbaat 60, gesuiwerde water, propyleenglikol, metielparabeen, propylhidroksibensoaat.
Preserveermiddels: metielhidroksibensoaat (0,15 % m/m) en propylhidroksibensoaat (0,05 % m/m).

Hoe SILBECOR lyk en die inhoud van die pak
SILBECOR is 'n reuklose, wit, homogene room.

SILBECOR sal in enige van die volgende verpakkingsmateriaal verpak word:
1. 250 g plastiekhouer
Swart blaasgevormde HDPE-houer met 'n swart polipropileen-dop.
2. 500 g plastiekhouer
Swart blaasgevormde HDPE-houer met 'n swart polipropileen-dop.
Nie alle pakgroottes mag bemark word nie.

Houer van die sertifikaat van registrasie
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Hierdie pamflet is laas hersien
01 Desember 2021

Registrasienommer
29/14.2/0338

Botswana: Silbecor 250 g: Reg. Nr. BOT1803410A Silbecor 500 g: Reg. Nr. BOT1803410B		S3 S3	
Namibië: Reg. Nr. 12/14.2/0153	NS2	Zimbabwe: Reg. Nr. 98/14.1.2/3422	PP10