SCHEDULING STATUS:
S4

PROPRIETARY NAME AND DOSAGE FORM:
SILBECOR (CREAM)

COMPOSITION:
Each gram of cream contains silver sulphadiazine 10,0 mg as active ingredient.
Inactive ingredients: arachis oil (hydrogenated), cetyl alcohol, polysorbate 60, propylene glycol.
Preservatives:
Methyl hydroxybenzoate 0,15 % m/m.
Propyl hydroxybenzoate 0,05 % m/m.

CATEGORY AND CLASS:
A14.2 Wound dressing

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
Silver sulphadiazine inhibits the growth *in-vitro* of pathogenic bacteria and fungi. Not all strains of a particular organism may be susceptible. Silver is released slowly from the preparation in concentrations that are selectively toxic to micro-organisms. Bacteria may develop resistance to silver sulphadiazine.
Pharmacokinetic properties
Sulphadiazine is slowly released by silver sulphadiazine when in contact with wound exudates. Up to 10 % of the sulfadiazine may be absorbed. Blood concentrations of 10 to 20 micrograms/ml have been reported although higher concentrations may be achieved when extensive areas of the body are treated. There is a possibility that some silver may also be absorbed.

INDICATIONS:
SILBECOR is a topical antibacterial medicine for the prevention and treatment of infections in wounds, burns, leg ulcers and pressure sores.

CONTRAINDICATIONS:
Hypersensitivity to silver sulphadiazine, sulphonamides or any of the other inactive ingredients of SILBECOR.
SILBECOR contains arachis oil (peanut oil). If you are allergic to peanuts or soya, do not use this medicine.
Sulphonamide therapy is known to increase the possibility of kernicterus. SILBECOR cream should therefore not be used in pregnant women, premature infants or in infants during the first months of life (refer to HUMAN REPRODUCTION).
Lactation (refer to HUMAN REPRODUCTION).
SILBECOR should not be used if hepatic or renal function becomes impaired.
Porphyria.

WARNINGS and SPECIAL PRECAUTIONS:
FOR EXTERNAL USE ONLY.
Patients sensitive to sulphonamides, furosemide, thiazide diuretics, sulphonylureas or carbonic anhydrase inhibitors may be sensitive to SILBECOR.
Caution is advised in patients known to have glucose-6-phosphate dehydrogenase deficiency. The use of SILBECOR cream in glucose-6-phosphate dehydrogenase deficient patients may cause haemolysis. Leukopenia (fall in white blood cell count) has been reported (refer to SIDE EFFECTS). In burn patients, this usually manifests in 2 – 3 days after treatment has commenced. The blood count should be monitored to ensure that it returns to normal within a few days (also refer to INTERACTIONS).
Appreciable amounts of sulphadiazine may be absorbed to produce systemic side effects, when SILBECOR is applied to a large area and when the lesion(s) is/are deep.
Systemic absorption of silver, resulting in argyria, with discolouration of the skin and sensorimotor neuropathy, can occur when SILBECOR is applied to large area wounds or over prolonged periods (refer to SIDE EFFECTS).
The risk of crystallisation in the urine may be reduced with the administration of fluids to maintain high urine output. Adequate fluid intake and normalisation of acid base balance is important (refer to SIDE EFFECTS).
Local skin sensitivity to SILBECOR may occur, especially when exposed to sunlight.
Treatment should be discontinued if a rash appears because of the danger of a severe allergic reaction (Stevens-Johnson syndrome) (refer to SIDE EFFECTS).
Sulphadiazine may displace serum bound bilirubin resulting in jaundice and kernicterus in premature neonates (refer to CONTRAINDICATIONS).
Elderly patients and patients with AIDS may be particularly prone to the adverse reactions.

INTERACTIONS:
SILBECOR may potentiate the effects of the following medicines:
- oral hypoglycaemic medicines
- oral anticoagulants
- methotrexate
- phenytoin.

High doses of SILBECOR can have a hypoglycaemic effect; the antidiabetic effect of the sulfonylurea compounds may be enhanced by SILBECOR.
The silver content of SILBECOR may inactivate enzymatic debriding medicines.
Concurrent use with cimetidine may increase the incidence of leukopenia (refer to SIDE EFFECTS and WARNINGS AND SPECIAL PRECAUTIONS).

HUMAN REPRODUCTION:
SILBECOR is contraindicated during pregnancy and lactation (refer to CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE:
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.

SIDE EFFECTS:
Blood and lymphatic system disorders
These effects are thought to be hypersensitivity effects:
Frequent: leukopenia (refer to WARNINGS AND SPECIAL PRECAUTIONS).
Less frequent:
- agranulocytosis
- aplastic anaemia
- thrombocytopenia
- hypoprothrombinaemia
- eosinophilia.

Endocrine disorders
Frequent: hypoglycaemia.
Frequency unknown: hypothyroidism.
Nervous system disorders
Frequency unknown: aseptic meningitis; ataxia; benign intracranial hypertension; convulsions; dizziness; drowsiness; fatigue; headache; insomnia; mental depression; peripheral or optic neuropathies; psychoses; vertigo.
Gastrointestinal disorders
Frequent: nausea; vomiting; anorexia; diarrhoea.
Hepato-biliary disorders
Frequency unknown: jaundice; kernicterus in premature neonates.
Skin and subcutaneous tissue disorder
Frequent: application site rash (including eczema and contact dermatitis); photosensitive reactions; exfoliative dermatitis; dermatitis; erythema nodosum; pruritis.
Less frequent: argyria.
Frequency unknown: toxic epidermal necrolysis; Stevens-Johnson syndrome; systemic lupus erythematosus.
Renal and urinary disorders
Frequent: nephrotoxic reactions (including interstitial nephritis and tubular necrosis); lumbar pain, haematuria, oliguria and anuria may also occur due to crystallisation in the urine.
Less frequent: renal failure.
General disorders and administration site conditions
Frequent: fever, application site burning.
Less frequent: local pain and irritation; fungal invasion of wound; anaphylaxis.
Frequency unknown: generalised hypersensitivity effects include:
- syndrome resembling serum sickness
- liver necrosis
- hepatomegaly, jaundice and myocarditis
- pancreatitis
- pulmonary eosinophilia
- fibrosing alveolitis
- vasculitis including polyarthritis nodosa.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Side effects may be exacerbated and exaggerated.
See SIDE EFFECTS. Treatment is symptomatic and supportive.

IDENTIFICATION:
Odourless, white homogenous cream.

PRESENTATION:
250 g and 500 g plastic jars.

STORAGE INSTRUCTIONS:
Store at or below 25 °C. Protect from light.
KEEP OUT OF SIGHT AND REACH OF CHILDREN

REGISTRATION NUMBER:
29/14.2/0338

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Biotech Laboratories (Pty) Ltd.
Ground Floor, Block K West, Central Park,
400 16th Road, Halfway House, Midrand, 1685
South Africa

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:
Date of registration: 29 August 1995
Date of most recently revised approved professional information:
05 May 2019

Zimbabwe: Reg. No. 98/14.1.2/3422	PP10
Namibia: Reg. No. 12/14.2/0153	NS2

SKEDULERINGSTATUS:
S4

EIENDOMSNAAM EN DOSEERVORM:
SILBECOR (ROOM)

SAMESTELLING:
Elke 1 g room bevat 10,0 mg silwersulfadiasien as aktiewe bestanddeel.
Onaktiewe bestanddele: aragis olie (gehidrogeneerde), setiel alkohol, polisorbaat 60, propileen glikol.
Preserveermiddels:
Metielhidroksiebensoaat 0,15 % m/m
Propielhidroksiebensoaat 0,05 % m/m

KATEGORIE EN KLASSIFIKASIE:
A14.2 Wonddekkings

FARMAKOLOGIESE WERKING:
Farmakodinamiese eienskappe
Silwersulfadiasien inhibeer die groei van patogeniese bakterieë en swamme *in-vitro*.
Nie alle stamme van 'n spesifieke organisme kan ontvanklik wees nie. Silwer word stadig vrygestel van die voorbereiding in konsentrasies wat selektiewelik toksies is vir mikro-organismes. Bakterieë mag 'n weerstand teen silwersulfadiasien ontwikkel.
Farmakokinetiese eienskappe
Sulfadiasien word stadig vrygestel deur silwersulfadiasien wanneer dit in kontak met wonduitskeidings kom. Tot 10 % van die sulfadiasien kan geabsorbeer word. Bloedkonsentrasie vlakke van 10 tot 20 mikrogram/ml is al aangemeld, hoewel hoër konsentrasies bereik kan word wanneer groter dele van die liggaam behandel word. Daar bestaan ook 'n moontlikheid dat sommige van die silwer geabsorbeer kan word.

INDIKASIES:
SILBECOR is 'n topikale antibakteriese medikasie vir die voorkoming en behandeling van geïnfekteerde wonde, brandwonde, been ulkusse en druksere.

KONTRAINDIKASIES:
Hipersensitiwiteit teenoor silwer sulfadiasien, sulfoonamiede of enige van die ander aktiewe bestandele van SILBECOR.
SILBECOR bevat aragis olie (grondboon olie), Indien allergieë teen grondbone en soja bekend is, moet die medikasie nie gebruik word nie.
Sulfoonamied-terapie is bekend daarvoor om die moontlikheid van kernikterus te verhoog. SILBECOR room moet verkieslik nie gebruik word in swanger vroue, premature babas of babas in die eerste paar maande van hul lewens nie. (verwys na MENSLIKE VOORTPLANTING)
Borsvoeding (verwys na MENSLIKE VOORTPLANTING)
SILBECOR moet nie gebruik word indien dit hepatiese of renale funksie gaan benadeel nie.
Porfirie.

WAARSKUWINGS en SPESIALE VOORSORGMAATREËLS:
SLEGS VIR UITWENDIGE GEBRUIK.
Pasiënte wat sensitiwiteit toon teenoor sulfoonamied, furosemied, tiasiediuretika, sulfonielureums of koolsuuranhidrase inhibeerders kan sensitief wees vir die gebruik van SILBECOR.
Pasiënte met bekende glukose-6-fosfaat dehidrogenase tekort, moet met sorg benader word. Die gebruik van SILBECOR room in pasiënte met glukose-6-fosfaat dehidrogenase tekort mag hemolise veroorsaak.
Leukopenie (verlaging van witbloedseltelling) is al aangemeld (verwys na NEWE-EFFEKTE). In brandwond pasiënte, manifesteer dit gewoonlik binne 2 – 3 dae na aanvang van behandeling. Die bloed telling moet gemonitor word om te verseker dat dit na normaal terugkeer binne 'n paar dae (verwys ook na INTERAKSIES).
Aansienlike hoeveelhede van sulfadiasien kan geabsorbeer word en tot sistemiese newe-effekte lei, wanneer SILBECOR op 'n groot oppervlak aangewend word en wanneer die letsel(s) diep is.
Sistemiese absorpsie van silwer wat argirie tot gevolg het met verkleuring van die vel en sensorimotor neuropatie kan voorkom wanneer SILBECOR aan groot area wonde of oor 'n verlengde tydperk aangewend word. (verwys na NEWE-EFFEKTE).
Die risiko van kristallisasie in die urine kan verlaag word met die inname van vloeistowwe om 'n hoë urienuitskeiding te handhaaf. Genoegsame vloeistof inname en normalisering van die suurbasisbalans is belangrik (verwys na NEWE-EFFEKTE).
Lokale velsensitiwiteit met die gebruik van SILBECOR kan plaasvind, veral met blootstelling aan sonlig.
Behandeling moet gestaak word indien 'n uitslag verskyn as gevolg van die gevaar van 'n erge allergiese reaksie (Stevens-Johnson sindroom) (verwys na NEWE- EFFEKTE).
Sulfadiasien kan serumgebonde bilirubien in premature pasgeborenes verplaas wat lei tot geelsug en kernikterus (verwys na KONTRAINDIKASIES).
Bejaarde pasiënte en pasiënte met VIGS kan veral vatbaar wees vir die negatiewe reaksies.

INTERAKSIES:
SILBECOR kan die uitwerking van die volgende geneesmiddels potensieer:
- orale hipoglisemiese medisyne
- orale anti-stolmiddels
- metotreksaat
- fenitoïen.

Hoë dosisse van SILBECOR kan 'n hipoglisemiese effek hê; die antidiabetiese effek van die sulfonielureum verbindings mag deur SILBECOR verhoog word.
Die silwer inhoud van SILBECOR kan die effek van ensiematiese debriderende middels deaktiveer.
Gelyktydige gebruik met simetidien kan die voorkoms van leukopenie verhoog (verwys na NEWE- EFFEKTE en WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS).

MENSLIKE VOORTPLANTING:
Die gebruik van SILBECOR word gekontraïndikeer tydens swangerskap en borsvoeding (verwys na KONTRAINDIKASIES).

DOSIS EN GEBRUIKSAANWYSINGS:
SILBECOR moet daagliks aangewend word in 'n laag van ongeveer 3 - 5 mm dik met 'n steriele handskoen of spatel. Die wond kan bedek word of oop gelos word. Een houer van die SILBECOR room behoort per pasiënt gebruik te word, enige oorblywende room moet na voltooiing van die behandeling weggegooi word.

NEWE-EFFEKTE:
Bloed en limfsisteem versteurings
Hierdie effekte is vermoedelik hipersensitiwiteitseffekte:
Algemeen: leukopenia (verwys na WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS).
Minder Algemeen:
- agranulositose
- aplastiese anemie
- trombositopenie
- hipoprotrombinemie
- eosinofilie

Endokriene versteurings
Algemeen: hipoglisemie.
Frekwensie onbekend: hipotiroïedisme.
Senuweestelsel versteurings
Frekwensie onbekend: aseptiese meningitis; ataksie; benigne intrakraniale hipertensie; konvulsies; duiseligheid; lomerigheid; moegheid; hoofpyn; slapeloosheid; geestelike depressie; perifere of optiese neuropatie; psigoses; vertigo.
Gastroïntestinale versteurings
Algemeen: naarheid; braking; anoreksie; diarree.
Hepato-bilière versteurings
Frekwensie onbekend: geelsug; kernikterus in premature pasgeborenes.
Vel en onderhuidseweefsel versteurings
Algemeen: uitslag; fotosensitiewe reaksies; eksfoliatiewe dermatitis; dermatitis; nodeuse eriteem.
Minder algemeen: argiria
Frekwensie onbekend: toksiese epidermale nekrolise; Stevens-Johnson sindroom; sistemiese lupus eritematose.
Renale en urienwegversteurings
Algemeen: nefrotoksiese reaksies (insluitend interstisiële nefritis en tubulêre nekrose); lumbale pyn; hematurie; oligurie en anurie kan ook voorkom as gevolg van kristallisasie in die urine.
Minder algemeen: nierversaking
Algemene versteurings en toedieningsomstandighede
Algemeen: koors, brand op die plek van toediening
Minder algemeen: lokale pyn en irritasie; swamindringing van die wond; anafilakse.
Frekwensie onbekend: algemene hipersensitiwiteitsreaksies sluit in:
- sindroom wat ooreenstem met serum siekte
- lewer nekrose
- hepatomegalie, geelsug en miokarditis
- pankreatitis
- pulmonêre eosinofilie
- fibrotiese alveolitis
- vaskulitis insluitende poliartritis nodosa.

BEKENDE SIMPTOME VAN OORDOSERING EN DIE BEHANDELING DAARVAN:
Newe-effekte mag vererger en oordrewe voorkom
Sien NEWE-EFFEKTE. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
Reuklose, wit homogene room.

AANBIEDING:
250 g en 500 g plastiek houers.

BERGINGSAANWYSINGS:
Bewaar teen of benede 25 °C. Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS

REGISTRASIENOMMER:
29/14.2/0338

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIE SERTIFIKAAT:
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Suid Afrika

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Zimbabwe: Reg. Nr. 98/14.1.2/3422	PP10
Namibia: Reg. Nr. 12/14.2/0153	NS2