Clean amended proposed patient information leaflet for 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
2. What you need to know before you use SILBECOR
3. How to use SILBECOR
4. Possible side effects
5. How to store SILBECOR
6. Contents of the pack and other information

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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Signed: