

SIVERPAN

Dermal Cream



Composition:

Each 1 g of SILVERPAN Dermal Cream contains:
Silver Sulfadiazine 10 mg and Dexpanthenol 50 mg.

Pharmacological Classification:

Antibacterial, skin moisturizer.

Intended Use (Common Use of the Drug):

Treatment of burns and ulcers and prevention of primary and secondary bacterial infections.

Mechanism of Action:

- Silver sulfadiazine: Silver sulfadiazine has broad antimicrobial activity. It is bactericidal for many gram-negative and gram-positive bacteria as well as being effective against yeast. Sufficient data have been obtained to demonstrate that silver sulfadiazine will inhibit bacteria that are resistant to other antimicrobial agents and that the compound is superior to sulfadiazine. Silver sulfadiazine acts only on the cell membrane and cell wall to produce its bactericidal effect.

- Dexpanthenol: Dexpanthenol enhances the movement of lipid and protein molecules in the corneum, which helps the skin to be hydrated. Dexpanthenol interacts with lipid molecules and proteins in the skin, helping to maintain skin moisture and flexibility. Dexpanthenol promotes epidermal regeneration by enhancing cell differentiation and lipid synthesis.

Pharmacokinetics:

- Silver sulfadiazine:

Absorption: Up to approx 10% of sulfadiazine and some silver may be absorbed; depending on the nature of the wound and treatment regimen.

Excretion: Silver slowly excreted via the faeces. Sulfadiazine via urine (6.6% within 5 days).

- Dexpanthenol: Dexpanthenol is easily absorbed through the skin. Convert to pantothenic acid and widely distributed in the body. High concentrations in tissues associated with skin, hair and nail. Discharge mainly through urine.

Indications:

- Use this medicine exactly as described in this leaflet or as directed by your doctor or pharmacist, consult your doctor if you are not sure.
- SILVERPAN is indicated for prevention and topical management of skin wounds, second- and third-degree burns, blisters, scratches, skin fissures, as well as post-burn care for minor burns and the treatment of dermatitis.

Contraindications:

- Patients who are hypersensitive to Silver Sulfadiazine or Dexpanthenol or any of the other ingredients in the preparation.
- Sulfonamides increase the risk of kernicterus, so SILVERPAN should not be used in late pregnancy, prenatally, or in newborn infants less than two months of age.

Side Effects:

- Like all medicines, this one can cause side effects, although not everyone experiences them.
- Some side effects may occur infrequently such as: skin necrosis, erythema multiforme, skin discoloration, burning sensation, rash, and interstitial nephritis. Mild allergic reactions such as itching caused by Dexpanthenol can occur, however, this condition is rare.
- Inform your doctor or pharmacist if you experience any side effects not listed in this leaflet.

Warnings & Precautions:

- Caution should be exercised when using a cream containing Silver Sulfadiazine in patients with glucose-6-phosphate dehydrogenase deficiency, as hemolysis may occur.
- Accumulation of Silver Sulfadiazine may occur in case of impaired hepatic and renal function and decreased drug elimination, so caution should be exercised when using the SILVERPAN.
- Dexpanthenol should be careful in people with bleeding or a high risk of bleeding, due to the ability to prolong the bleeding time.
- Limit Dexpanthenol exposure to the eyes to avoid discomfort.
- There is potential cross-sensitivity between silver sulfadiazine and other sulfonamides. If allergic reactions attributable to treatment with silver sulfadiazine occur, continuation of therapy must be weighed against the potential hazards of the particular allergic reaction.

Drug and Food Interactions:

- Tell your doctor or pharmacist if you are using, have recently used or might use any other drugs, and for how long you will be using the drug.
- Silver Sulfadiazine may alter the effect of oral hypoglycemic agents and phenytoin if applied to large areas of skin.
- No drug interactions have been reported with Dexpanthenol.

Pregnancy & Lactation & Fertility:

Pregnancy:

Silver sulfadiazine: Pregnancy Category B, this drug should be used during pregnancy only if clearly justified, especially in pregnant women approaching or at term.
Dexpanthenol can be used by pregnant or lactating women under the doctor's prescription.

Lactation: It is not known whether silver sulfadiazine is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from sulfonamides, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Fertility: The effect of SILVERPAN on fertility after topical application in humans has not been studied.

Effects on ability to drive and use machines:

SILVERPAN cream does not affect your ability to drive or use machines.

Method of use:

- Use this drug exactly as your doctor or pharmacist has prescribed it. Ask your doctor if you are not sure.
- Immediate initiation of treatment for a burn patient is of paramount importance to control of shock and pain.
- Burn wounds should be cleaned and debrided, and the SILVERPAN should be applied under sterile conditions.
- The entire burn area should be covered with the SILVERPAN at all times.
- The SILVERPAN should be applied once or twice daily. The SILVERPAN should be reapplied to areas where it has been involuntarily removed.
- dressings may be applied if the patient's condition so requires.
- Treatment should be continued until no infection or significant adverse reactions have occurred.
- Reapply SILVERPAN immediately after using water to wash the burn.
- Inform your doctor or pharmacist if you forget to apply the cream and before stopping its use.

Overdoses/Toxicity/methods of treatment:

- Silver Sulfadiazine: Should a massive absorption of the drug occur, its elimination through the urine must be enhanced with the ingestion of abundant bicarbonate liquid preparations. In the event of serious crystalluria, urethral catheterization may be necessary.
- Dexpanthenol is well tolerated and non-toxic when using high doses. There have been no reports of the use of Dexpanthenol overdose.

Physical Properties:

White to off white cream, homogeneous, free of foreign bodies.

Storage Conditions:

Store at a temperature below 25° C.

Keep out of reach of children.

Keep tube tightly closed.

Packaging:

Each SILVERPAN Carton box contains Aluminum Tub of 30 g.

