140.00 mm

Silverex Cream 1% w/w
(Silver sulfadiazine)

سلوریکس کریم 1%
(سلورسلفاڈایازین)

COMPOSITION:
Each gram contains:
Silver sulfadiazine .....10 mg
(USP Specifications)

DESCRIPTION:
Silverex Cream 1% is a soft, white, water-miscible cream containing the antimicrobial agent silver sulfadiazine in micronized form. It spreads easily and can be washed off readily with water.

MECHANISM OF ACTION:
The mechanism of silver sulfadiazine's antibacterial action has not been fully elucidated. After exposure to the drug, structural changes in the bacterial cell membrane occur, including distortion and enlargement of the cell and a weakening of the cell wall membrane. This is accompanied by reduced viability in sensitive strains due to interference with macromolecular synthesis. The sulfadiazine moiety also provides a bacteriostatic action against sensitive organisms. The antibacterial action of the silver salt of sulfadiazine does not appear to depend on inhibition of folic acid synthesis. Its action is not antagonized by p-aminobenzoic acid.

INDICATIONS:
Silverex cream 1% (silver sulfadiazine) is a topical antimicrobial drug indicated as an adjunct for the prevention and treatment of wound sepsis in patients with second- and third degree burns.

DOSAGE & ADMINISTRATION:
Prompt institution of appropriate regimens for care of the burned patient is of prime importance and includes the control of shock and pain. The burn wounds are then cleansed and debrided, and silver sulfadiazine is applied under sterile conditions. The burn areas should be covered with cream at all times. The cream should be applied once to twice daily to a thickness of approximately 1/16 inch. Whenever necessary, the cream should be reapplied to any areas from which it has been removed by patient activity. Administration may be accomplished in minimal time because dressings are not required. However, if individual patient requirements make dressings necessary, they may be used. Reapply immediately after hydrotherapy.
Treatment with silver sulfadiazine Cream should be continued until satisfactory healing has occurred, or until the burn site is ready for grafting. The drug should not be withdrawn from the therapeutic regimen while there remains the possibility of infection except if a significant adverse reaction occurs.

PHARMACOKINETICS:
There is evidence that in large area wounds and/or after prolonged application, systemic absorption of silver can occur causing clinical argyria. The sulfadiazine readily diffuses across wounds and enters the general circulation. The degree of uptake will significantly depend upon the nature of the wound and the dosing regimen. Sulfadiazine is excreted in the urine.

WARNINGS:
Absorption of silver sulfadiazine varies depending upon the percent of body surface area and the extent of the tissue damage. Although few have been reported, it is possible that any adverse reaction associated with sulfonamides may occur. Some of the reactions, which have been associated with sulfonamides, are as follows: blood dyscrasias including agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, and hemolytic anemia; dermatologic and allergic reactions, including life-threatening cutaneous reactions [Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and exfoliative dermatitis gastrointestinal reactions; hepatitis and hepatocellular necrosis; CNS reactions; and toxic nephrosis. 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. Fungal proliferation in and below the eschar may occur. However, the incidence of clinically reported fungal superinfection is low. The use of silver sulfadiazine in some cases of glucose-6 phosphate dehydrogenase - deficient individuals may be hazardous, as hemolysis may occur.

PRECAUTIONS:
General
If hepatic and renal functions become impaired and elimination of drug decreases, accumulation may occur and discontinuation silver sulfadiazine should be weighed against the therapeutic benefit being achieved. In considering the use of topical proteolytic enzymes in conjunction with silver sulfadiazine, the possibility should be noted that silver may inactivate such enzymes.
Laboratory Tests
In the treatment of burn wounds involving extensive areas of the body, the serum sulfa concentrations may approach adult therapeutic levels (8 mg% to 12 mg %). Therefore, in these patients it would be advisable to monitor serum sulfa concentrations. Renal function should be carefully monitored and the urine should be checked for sulfa crystals. Absorption of the propylene glycol vehicle has been reported to affect serum osmolality, which may affect the interpretation of laboratory tests.
Pregnancy
Pregnancy Category B.
There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly justified, especially in pregnant women approaching or at term.
Nursing Mothers
It is not known whether silver sulfadiazine is excreted in human milk. However, sulfonamides are known to be excreted in human milk, and all sulfonamide derivatives are known to increase the possibility of kernicterus. Because of the possibility 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.

SIDE EFFECTS
Several cases of transient leukopenia have been reported in patients receiving silver sulfadiazine therapy. Leukopenia associated with silver sulfadiazine administration is primarily characterized by decreased neutrophil count. Maximal white blood cell depression occurs within 2 to 4 days of initiation of therapy. Rebound to normal leukocyte levels follows onset within 2 to 3 days. Recovery is not influenced by continuation of silver sulfadiazine therapy. An increased incidence of leukopenia has been reported in patients treated concurrently with cimetidine. Other infrequently occurring events include skin necrosis, erythema multiforme, skin discoloration, burning sensation, rashes, and interstitial nephritis. Reduction in bacterial growth after application of topical antibacterial agents has been reported to permit spontaneous healing of deep partial-thickness burns by preventing conversion of the partial thickness to full thickness by sepsis.
However, reduction in bacterial colonization has caused delayed separation, in some cases necessitating escharotomy in order to prevent contracture.

CONTRAINDICATIONS:
Silver sulfadiazine is contraindicated in patients who are hypersensitive to silver sulfadiazine or any of the other ingredients in the preparation. Because sulfonamide therapy is known to increase the possibility of kernicterus, it should not be used on pregnant women approaching or at term, on premature infants, or on newborn infants during the first 2 months of life.

STORAGE & INSTRUCTIONS:
Store between 20-25°C. Do not freeze or refrigerate. Protect from heat, sunlight and moisture. Keep away from the reach of the children.
To be sold on the prescription of a registered medical practitioner only.
FOR EXTERNAL USE ONLY.

HOW SUPPLIED:
Silverex Cream: 15g, 50g, 250g.

خوراک وطریقہ استعمال:
ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

ہدایات:
دوا کو ۲۰-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔ دھوپ، گرمی، نمی اور منجمد ہونے سے بچائیں۔ ریفریجریٹر میں نہ رکھیں۔ بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔
صرف بیرونی استعمال کے لئے ہے۔

Manufactured by:
PHARMASOL
PRIVATE LIMITED
Plot # 549,Sundar Industrial Estate,
Lahore, Pakistan.

210.00 mm