SILFAZINE CREAM

Composition:
Silver Sulphadiazine 1% w/w

Product Description: A white, smooth and soft cream.

Pharmacodynamics:
Silver sulphadiazine has broad anti-microbial activity against gram-positive and gram-negative bacteria, yeasts and fungi. Silver sulphadiazine acts only on the cell membrane and cell wall to produce its bactericidal effect.

Pharmacokinetics:
Silver sulphadiazine is slowly metabolised in contact with wound exudates. Up to about 10% of the sulphadiazine may be absorbed; concentrations in blood of 10 to 20µg per ml have been reported although higher concentrations may be achieved when extensive areas of the body are treated. Probably not more than 1% of the silver content is absorbed.

Indication:
It is indicated as an adjunct for the prevention and treatment of wound sepsis in patients with second and third-degree burns.

Recommended Dosage:
The cream should be applied once to twice daily to a thickness of approximately 1/16 inch on the burn areas. It should be continued until satisfactory healing has occurred or until the burn site is ready for grafting.

Route of Administration: Topical

Contraindications:
Silver sulphadiazine should not be used at term pregnancy, on premature infants or on newborn infants during the first month of life because sulfonamide therapy is known to increase the possibility of kernicterus.

Warnings and Precautions:
Silver sulphadiazine cream should not generally be used on patients with a known sensitivity to sulphonamides and should be used with care in the presence of hepatic or renal impairment. Because of the possibility of kernicterus, it should not be used in pregnant women near term or in newborn infants. Caution of use is required in patients known to be sensitive to systematic sulphonamides and in individuals known to have glucose-6-phosphate dehydrogenase deficiency. Fatalities associated with administration of sulphonamides and trimethoprim, either alone or in combination, have occured due to severe reactions, including Steven-Johnson syndrome, toxic epidermal necrolysis and other reactions. The drug should be discontinued at the first appearance of skin rash or any sign of adverse reaction.

Interactions with Other Medicaments:
Topical enzyme preparations that contain collagenase or papain may be inactivated by the silver content of silver sulphadiazine if used concomitantly.

Pregnancy and Lactation:
Due to the possibility of kernicterus caused by sulfonamide derivatives, this drug should be used during pregnancy and lactation only if clearly justified.

Side Effects:
It is frequently difficult to distinguish between an adverse reaction due to silver sulphadiazine cream and reactions that may occur due to the concomitant use of other therapeutic agents used in the treatment of a patient having a severe wound burn. About 2.5% of patients treated with silver sulphadiazine, the separation of the eschar may be delayed and fungal invasion of the wound may occur. Since significant quantities of silver sulphadiazine are absorbed, it is possible that any of the adverse reactions attributable to sulfonamides may occur. Local reactions such as burning, itching and skin rash may occur. Leucopenia.

Symptoms and Treatments of Overdose:
Symptoms of overdosage as stated in side effects. Severe hypersensitivity reactions may require treatment with corticosteroids.

Storage Conditions: Store at or below 30°C. Protect from light.

Pack Sizes: A jar of 400g, 450g and 500g.
A tube of 15g, 30g and 50g.

Shelf-life: 3 years.

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.

Manufacturer & Product Registration Holder:
SUNWARD PHARMACEUTICAL SDN. BHD.
No. 9, 11 & 17, Jalan Kempas 4,
Taman Perindustrian Tampoi Indah,
81200 Johor Bahru, Johor, Malaysia.

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