Burna® Cream

Silver sulfadiazine USP 1%

Composition
Burna® : Each gram cream contains 10 mg Silver Sulfadiazine USP.

Pharmacology
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. The silver sulfadiazine molecule dissociates and the silver moiety is bound to the bacterial cells. It is believed that, after penetrating the cell wall, the silver moiety is attached to deoxyribonucleic acid (DNA) and prevents bacterial cell proliferation. There is approximately 100 times more DNA in mammalian cells than in bacterial cells. It is thought that the ratio of silver sulfadiazine to bacterial DNA is sufficiently high to prevent bacterial division but the corresponding ratio to epithelial DNA is low enough not to block epithelial cell regeneration. The sulfadiazine moiety also provides a bacteriostatic action against sensitive organisms. In adults, up to 10% of the sulfadiazine may be absorbed and 60 to 85% of the absorbed amount is excreted in the urine. In children with 13% body surface area burns, the urinary sulfadiazine concentration was 31.8 mg/L.

Indication
1. The topical prophylaxis against bacterial colonization and infection in burn wounds. 2. The topical antibacterial management of certain contaminated or infection-prone wounds, other than burns.

Dosage & Administration
The burn wounds are cleansed, and **Burna®** is applied over the burn wound. The burn areas should be covered with **Burna®** at all times. The cream should be applied once to twice daily to a thickness of approximately 1/16 inches or 1.5 mm. Whenever necessary; the cream should be reapplied to any areas from which it has been removed by patient activity. If individual patient requirements make dressings necessary, they may be used. Reapplication should be ensured immediately after hydrotherapy. Treatment with **Burna®** should be continued until satisfactory healing is 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 The drug should not be withdrawn from the therapeutic regimen while there remains the possibility of infection except if a significant adverse reaction occurs.

Contraindication
It is contraindicated in-patients who are hypersensitive to it or any of the other ingredients in the preparation. 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.

Side Effect
Several cases of transient leukopenia have been reported in-patients receiving Silver Sulfadiazine therapy. Other infrequently occurring events include skin necrosis, erythema multiform, skin discoloration, burning sensation, rashes, and interstitial nephritis.

Precaution
General If hepatic and renal functions become impaired and elimination of drug decreases, accumulation may occur and discontinuation of this should be weighed against the therapeutic benefit being achieved. In considering the use of topical proteolytic enzymes in conjunction with it, the possibility should be noted that silver might 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.

Use in Pregnancy and Lactation
Teratogenic Effects: Pregnancy Category B. 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. 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. Pediatric Use Safety and effectiveness in pediatric patients have not been established.

Drug Interaction
Enzymatic debriding agents: Silver sulfadiazine may inactivate enzymatic debriding agents, thus the concomitant use of these compounds may be inappropriate. Oral hypoglycemic agents and phenytoin: In patients with large area burns where serum sulfadiazine levels may approach therapeutic levels, the action of oral hypoglycemic agents and phenytoin may be potentiated and it is recommended that blood levels be monitored. Cimetidine: In-patients with large area burns, it has been reported that co-administration of Cimetidine may increase the incidence of leukopenia.

Storage
Store in a cool and dry place, protected from light. Keep out of reach of the children.

How Supplied
Burna® : Each pack has a laminated tube containing 25 gram cream.

Manufactured by :

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH