

# Silzin Cream

Silver Sulphadiazine BP 1%

## Composition:

Each gram of Silzin cream contains Silver Sulphadiazine BP 10 mg.

## Description:

Silzin (Silver Sulphadiazine 1% cream) is the silver salt of N<sub>1</sub> (Pyrimidin-2-yl) sulphanilamide. It is a local chemotherapeutic agent, used topically for the prevention & treatment of infection of wounds from burns. It has a broad antibacterial spectrum including virtually all microbial species likely to infect burn wounds. It is also an effective agent against *Candida albicans* and other fungi. It has a bactericidal action in contrast to Sulphadiazine. The silver salt acts primarily on the cell membrane and cell wall. The mechanism of Silver Sulphadiazine'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. Silzin cream (Silver Sulphadiazine) disintegrates in the burn wound, thereby causing a slow and sustained release of silver ions 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 DNA and prevents bacterial cell proliferation. It is thought that the ratio of Silver Sulphadiazine 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 Sulphadiazine moiety also provides a bacteriostatic action against sensitive organisms. Silzin penetrates into the necrotic tissue and exudate. This effect is very important in view of the fact that systemic antibiotics are not effective against the bacterial flora of vascular burn necrosis. Silver Sulphadiazine is slowly metabolized in contact with wound exudates. The compound is painless upon application. It also has a pleasant cooling effect to the burnt surface.

## Indication:

- Prophylaxis and treatment of infection in burn wounds
- As an adjunct to short-term treatment of infection in
  - a. Leg ulcers
  - b. Pressure sores
- As an adjunct to prophylaxis of infection in
  - a. Skin graft donor sites
  - b. Extensive abrasions
- Conservative management of finger-tip injuries

## Dosage & Administration:

The burn wounds are to be cleansed properly and Silzin cream is to be applied over the burn wound. The cream should be applied once to twice daily to a thickness of approximately 3-5 mm. Whenever necessary, the cream should be re-applied to any areas from which it has been removed by patient activity. If individual patient require dressings, they may be used. Re-application should be ensured immediately after hydrotherapy. Treatment with Silzin cream 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 where there is possibility of infection except if any significant adverse reaction occurs.

## Contraindication:

It is contraindicated in patients who are hypersensitive to sulfonamides. 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.

## Use in Children

The cream should not be used on premature infants or on newborn infants during the first 2 months of life.

## Side-effects:

Local reactions such as skin necrosis, skin discoloration, erythema multiforme, burning sensation, itching, rashes and interstitial nephritis have been reported in patients treated with Silver Sulphadiazine. The separation of eschar may be delayed and fungal invasion of the wound may occur. Transient leucopenia has occurred although its association with application of Silver Sulphadiazine has not been consistently confirmed. Systemic absorption of silver, resulting in argyria, can occur when Silver Sulphadiazine is applied to large area wounds or over prolonged periods.

## Use in Pregnancy and Lactation

**Pregnancy:** It is a drug of pregnancy category B. As Sulphonamide therapy is known to increase the possibility of kernicterus, Silver Sulphadiazine 1% cream should not be used on pregnant women approaching or at term except in cases when the potentially life-saving benefits of the medication outweigh possible hazards to the foetus.

**Lactating mothers:** It is not known whether Silver Sulphadiazine 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.

## Precautions

Caution is required in the presence of hypersensitivity to Sulphonamides because of possible allergic reactions, in patients with inborn glucose-6-phosphate dehydrogenase deficiency, as haemolysis may occur after the application of the cream to the large body surface area; as well as in the presence of hepatic and renal dysfunction. When treatment with Silzin cream involves prolonged administration or large burn surfaces, the white blood cell count should be monitored, as leukopenia may occur.

In considering the use of topical photolytic enzymes in conjunction with Silzin, the possibility should be noted that silver may inactivate such enzymes. In the treatment of burn wounds involving extensive areas of the body, the serum sulpha concentration may approach adult therapeutic levels (8 to 12 mg/100 ml). Therefore in these patients, it would be advisable to monitor serum sulpha concentration. Renal function should be carefully monitored. The urine should be checked for sulpha crystals.

## Drug Interaction

**Enzymatic debriding agents:** Silver Sulphadiazine 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 Sulphadiazine 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 a dry place (below 25°-30° C) & away from light. The tube should be tightly closed. Keep out of the reach of children.

## How Supplied:

Aluminium collapsible tube containing 25 gm cream.

Manufactured by :

 **KEMIKO PHARMACEUTICALS LTD.**  
Bangladesh