

Sibalyn®

Silver Sulfadiazine

Description

Sibalyn® cream is a preparation of silver sulfadiazine which is a local chemotherapeutic agent for prevention and treatment of burn wound infections. Silver sulfadiazine disintegrates in the burn wound and thereby causing a slow and sustained release of silver ions. Silver ions bind to bacterial deoxyribonucleic acid, thus inhibiting the growth and multiplication of bacterial cells without affecting the cells of the skin and subcutaneous tissue. Silver sulfadiazine cream has a broad antibacterial spectrum including virtually all microbial species likely to infect the burn wound: *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, strains of *Proteus* and *Klebsiella*; it is also effective against *Candida albicans* and other fungi. Silver sulfadiazine 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.

Indications

Sibalyn® cream is indicated in:

- Prophylaxis and treatment of infection in burn wounds
- Treatment for deep neglected wounds
- As an adjunct to short-term treatment of infection in leg ulcers and pressure sores
- As an adjunct to prophylaxis of infection in skin graft donor sites and extensive abrasions
- Conservative management of finger-tip injuries

Dosage and administration

To be applied topically.

Burns: The burn wound should be cleaned and **Sibalyn®** cream applied over all the affected areas to a depth of 3-5mm. Best result will be achieved if sterile gloved hand and/or sterile spatula is used. Where necessary, the cream should be re-applied to any area from which it has been removed by patient activity. In burns, **Sibalyn®** cream should be re-applied at least every 24 hours or more frequently if the volume of exudate is large.

Hand burns: Before application of **Sibalyn®** cream to the burn, the whole hand should be enclosed in a clear plastic bag or glove. The patient should be encouraged to move the hand and fingers. The dressing should be changed when an excessive amount of exudate has accumulated in the bag.

Leg Ulcers/Pressure Sores: The cavity of the ulcer should be filled with **Sibalyn®** Cream to a depth of at least 3-5mm. As **Sibalyn®** Cream can cause maceration of normal skin on prolonged contact, care should be taken to prevent spread onto non-ulcerated areas. Application of **Sibalyn®** Cream should be followed by an absorbent pad or gauze dressing, with further application of pressure bandaging as appropriate for the ulcer. The dressings should normally be changed daily but for wounds which are less exudative, less frequent changes (every 48 hours) may be acceptable. Cleansing and debriding should be performed before application of **Sibalyn®** cream. **Sibalyn®** cream is not recommended for use in leg or pressure ulcers that are very exudative.

Finger-Tip Injuries: Haemostasis of the injury should be achieved prior to the application of a 3-5mm layer of **Sibalyn®** cream. A conventional finger dressing may be used. Alternatively water proof adhesive tape can be used on finger covered by a plastic or surgical glove. Dressings should be changed every 2-3 days.

Use in Pregnancy and Lactation

The safety of silver sulfadiazine in pregnancy and lactation has not been established. Although animal studies have not shown any hazard, adequate studies in pregnant women have not been performed. Therefore use of silver sulfadiazine in pregnancy only if benefit is likely to be greater than the possible risk to the foetus. Since all sulphonamides increase the possibility of kernicterus, caution is required in nursing mothers.

Use in children

Silver sulfadiazine should not be used on premature infants or on new born infants during the first two months of life.

Side-effects

The most common side effects are allergic reactions including burning, itching and rashes; argyria reported following prolonged use. Transient leucopenia may occur in patients receiving silver sulfadiazine therapy.

Contraindications

Silver sulfadiazine cream is contraindicated in patients known to be hypersensitivity to silver sulphamide or to other components of the preparation such as cetyl alcohol or propylene glycol. Because sulphonamide therapy is known to increase the possibility of kernicterus, silver sulphadiazine cream should not be used in pregnant women at term, in premature infants or in infants during the first months of life. It should not be used if hepatic and renal functions become impaired or if the condition of porphyria is suspected.

Precautions

Silver sulfadiazine cream should be used with caution in the presence of significant hepatic or renal impairment or if the condition of porphyria is suspected. Caution of use is required in patients known to be sensitive to systemic sulphonamides and in individuals known to have glucose-6-phosphate dehydrogenase deficiency and concomitant use with topical proteolytic enzymes. Use of silver sulfadiazine cream may delay separation of burn eschar and may alter the appearance of the burn wounds.

Drug interactions

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.

Pharmaceutical precautions

Store in a cool & dry place. Protect from light.

Presentation

Sibalyn[®] cream: Each gram cream contains 10 mg Silver Sulfadiazine USP.

Package quantities

Sibalyn[®] cream : Tube of 25 g.
: Jar of 250 g.

® Registered Trade Mark



ACI Limited

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