Drugfield PHARMACEUTICALS LIMITED

SUMMARY OF PRODUCT CHARACTERISTICS

Drumazine® (Silver Sulphadiazine 1.0%) Cream

1 NAME OF THE MEDICINAL PRODUCT

Drumazine® (Silver Sulphadiazine 1.0%) Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains Silver Sulphadiazine 1.0%

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream (Semi-solid)

4 Clinical particulars

4.1 Therapeutic indications

Drumazine® cream is indicated for the prophylaxis and treatment of infection in burn wounds. Drumazine® cream may also be used as an aid to the short-term treatment of infection in leg ulcers and pressure sores, and as an aid to the prophylaxis of infection in skin graft donor sites and extensive abrasions. Drumazine® cream is also indicated for the conservative management of finger-tip injuries where pulp, nail loss and/or partial loss of the distal phalanx have occurred.

Posology and method of administration

Posology

Important Dosage and Administration Instructions

Dead tissue should be removed from the wound. Apply this medication to the affected skin area using sterile technique. The wound should be covered with the cream at all times. Dressings may be applied over the cream, but only if needed.

The layer of medication should be 1-2 millimeters. Treatment usually continues until the wound is completely healed, Use once or twice daily

Method of administration

Topical administration

4.2 Contraindications

As sulphonamides are known to cause kernicterus, Drumazine Cream should not be used at, or near term pregnancy, on premature infants or on newborn infants during the first months of life. Sulpha allergy, hypersensitivity to any of the components, impaired renal or liver function.

4.3 Special warnings and precautions for use

Drumazine cream should be used with caution in the presence of significant hepatic or renal impairment. 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. Use of Drumazine cream may delay separation of burn eschar and may alter the appearance of the burn wounds.

4.4 Interaction with other medicinal products and other forms of interaction

Clinically Significant Drug Interactions with Silver Sulphadiazine

As silver may inactivate enzymatic debriding agents, their concomitant use may be inappropriate. In large-area burns where serum sulfadiazine levels may approach therapeutic levels, it should be noted that the effects of systemically administered drugs may be altered. This can especially apply to oral hypoglycaemic agents and to phenytoin. In the case of these drugs, it is recommended that blood levels should be monitored as their effects can be potentiated.

Pregnancy and Lactation

Pregnancy

For Drumazine cream no clinical data on exposed pregnancies are available, although animal studies have not shown any hazard. Since all Sulphonamides increase the risk of kernicterus, Drumazine cream should not be used in pregnant females at term and caution is required in nursing mothers.

Lactation

Systemically sulphadiazine can be excreted in breast milk although at concentrations 15 -35% of those found in serum.

4.5 Effects on ability to drive and use machines

None known

4.6 Undesirable 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.

Skin disorders: Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters.

Immune disorders: Hypersensitivity including anaphylactic shock.

4.7 Overdose

Over dosage with Drumazine® cream is unlikely to occur however,

Repeated Topical Application

Frequently repeated topical application on the same site could theoretically lead to skin irritation. However, since the product is only intended for minor skin trauma, extensive exposure is unlikely.

Accidental or Deliberate Ingestion

The product would only be expected to be harmful if orally ingested in very large quantities. This is unlikely due to the unpleasant taste of the product. In such a case the primary concern would be the phenol intake which can cause nausea, vomiting, diarrhoea and headache.

Treatment

1. Gastric lavage with water and charcoal.
2. Administration of demulcents such as egg white or milk and supportive measures.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamics

Silver sulfadiazine has bacteriostatic and bactericidal properties. This combination provides a wide spectrum of antimicrobial activity.

4.8 Pharmacokinetic properties

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.

4.9 Preclinical safety data

None stated

5 PHARMACEUTICAL PARTICULARS

5.1 List of excipients

Cetomacrogol 1000, Glyceryl Monostearate, Ceto-Stearyl Alcohol, Polysorbate, Liquid Paraffin (Heavy), Propylene Glycol, Methyl Paraben, Purified Water

5.2 Incompatibilities

Not applicable

5.3 Shelf life

36 Months

5.4 Special precautions for storage

Store below 30°C. Protect from light and moisture.

5.5 Nature and contents of container and special equipment for use, administration or implantation

Drumazine® Cream is presented in 25g tube with leaflet enclosed

5.6 Special precautions for disposal and other handling

No special requirements.

6 APPLICANT/MANUFACTURER

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