SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Silver sulfadiazine 1% w/w cream BP.

Galenicos burn cream.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition.

Active Ingredient

Silver Sulfadiazine 1%.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Topical cream.

A white to off-white, well-formed, smooth, lump free, and consistent cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Antimicrobial preparation for local treatment of burns, infected pressure sores and leg ulcers.

4.2 Posology and method of administration

Silver sulfadiazine 1% w/w cream BP should be applied in a layer approximately 3-5 mm thick with a sterile, gloved hand or spatula, to completely cover the burn area. Ordinarily, blisters are not opened, but loose tissue is generally removed prior to application.

After application of Silver sulfadiazine 1% w/w cream BP, the wound should either be left exposed or covered with a fine mesh gauze and an elastic mesh bandage. The exposure method is preferable in some patients (such as children) and for certain parts of the body (face, genitalia, etc.). When the wound is exposed, Silver sulfadiazine 1% w/w cream BP should be reapplied at about 12-hour intervals, or more frequently if the medication is rubbed off on the bedding. When dressings are used, they should be changed daily or on alternate days. Use of dressings serves to press the medication firmly against the wound, helps keep the area moist, reduces evaporative water loss and prevents drying/caking of the medication.

Silver sulfadiazine 1% w/w cream BP dressings can usually be left in place for about 48 hours during the first 2 weeks post burn. Subsequently, necrotic tissue undergoes proteolytic decomposition, producing considerable exudate which dilutes the drug and necessitates more

frequent dressing changes. When feasible, patients should be bathed daily as an aid in debridement. A whirlpool bath is particularly helpful, but patients may be bathed in bed or in a shower.

With silver sulfadiazine 1% w/w cream BP treatment, there will generally an absence of infection, and examination of the wound will reveal soft pliable eschars. These will separate gradually, leaving a clear granulating surface. In partial-thickness burns, the generating epithelium often appears in about 2 weeks, and burns initially classified as full-thickness injuries often heal within 5 weeks without grafting.

In leg ulcers, silver sulfadiazine 1% w/w cream BP should be applied followed by an absorbent gauze dressing and a support bandage, e.g. 10 cm elastic bandage. Care should be taken not to spread silver sulfadiazine 1% w/w cream BP on to non-ulcerated skin, and it should not be used on every wet ulcer. The dressing should be changed at least 3 times a week, and desloughing and cleansing should be carried out at the same time.

Any silver sulfadiazine 1% w/w cream BP remaining at the end of treatment should be discarded.

Treatment with silver sulfadiazine 1% w/w cream BP should be continued until satisfactory healing has occurred, or until the burn site is ready for grafting. The drug should not be withdrawn from the therapeutic regimen while the possibility of infection remains, unless a significant side effect occurs.

4.3 Contraindications

As sulfonamides are known to cause kernicterus, Silver sulfadiazine 1% w/w cream BP should not be used at, or near term of pregnancy, on premature infants or on newborn infants during the first months of life.

Silver sulfadiazine 1% w/w cream BP is also contraindicated in patients known to be hypersensitive to silver sulphadiazine or to other components of the preparation such as cetostearyl alcohol or propylene glycol.

4.4 Special warnings and precautions for use

Silver sulfadiazine 1% w/w cream BP 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 silver sulfadiazine 1% w/w cream BP cream may delay separation of burn eschar and may alter the appearance of the burn wounds.

Important information on excipients

This medicine contains 7.85 grams of propylene glycol (E 1520) in 100 grams of cream. Propylene glycol may cause skin irritation. Do not use this medicine in babies less than 4

weeks old with open wounds or large areas of broken or damaged skin (such as burns) without talking to your doctor of pharmacist.

This medicine contains cetostearyl alcohol, which may cause local skin reaction (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

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 systematically administered medicines may be altered.

This can especially apply to oral-hypoglycaemic agents and to phenytoin. In the case of these medicines, it is recommended that blood levels should be monitored as their effect can be potentiated.

4.6 Fertility, pregnancy and breastfeeding

For silver sulfadiazine 1% w/w cream BP no clinical data on exposed pregnancies are available, although animal studies have not shown any hazard.

Since all sulphonamides increase the risk of kernicterus, silver sulfadiazine 1% w/w cream BP should not be used in pregnant females at term and caution is required in nursing mothers. Systemically absorbed sulphadiazine can be excreted in breast milk although at concentrations 15-35% of those found in serum.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Blood and lymphatic tissue disorders

Common: Leucopenia

Leukopenia has been reported in 3-5% of burns patients treated with silver sulfadiazine 1% w/w cream BP. This may be a drug related effect, and often manifests itself 2-3 days after treatment has commenced. It is usually self-limiting and therapy with silver sulfadiazine 1% w/w cream BP does not usually need to be discontinued, although the blood count must be monitored to ensure that it returns to normal within a few days.

General disorders & administration site conditions

Common: Application site burning

Renal and Urinary Disorders

Very rare: renal failure

Skin & Subcutaneous Tissues Disorders

Common: Pruritis, Application site rash (including eczema and contact dermatitis).

Rare: Argyria

There is evidence that in large area wounds and/or after prolonged application, systemic absorption of silver can occur causing clinical argyria.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the e-PV desktop applications (https://drive.google.com/file/d/16hwTz0587ZWtSWadbBAMwQPOD_KSExZP/view) or search for e-PV Mobile applications on the Google Play or Apple App Store.

4.9 Overdose

Not likely to occur with normal usage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological Classification: 14.1.2 Topical anti-infectives: Sulphonamides

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

5.2 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.

5.3 Preclinical safety data

No further information available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin heavy 368 BP

White soft paraffin BP

Propylene glycol BP

Methyl Hydroxybenzoate BP

Cetostearyl alcohol BP

Sodium Lauryl Sulphate BP

Purified water BP

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store above 30°C in tightly closed containers. Do not freeze. Keep container tightly closed.

6.5 Nature and contents of container

Silver sulfadiazine 1% w/w cream BP is available in pack sizes of 100 g, 300 g and 500 g and is packaged in white polypropylene (PP) jars and with PP screw caps.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7. APPLICANT

Cospharm Pharmaceuticals

Stand 12896, Madokero Industrial Area

Harare, Zimbabwe

8. MANUFACTURER

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9. REGISTRATION DETAILS

Zimbabwe registration number: 2023/14.1.2/6396

Zimbabwe category for distribution: Pharmacy Medicines (P.)

10. DATE OF REVISION OF THE TEXT

May 2023