National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

AFTERBURN / SILVER SULFADIAZINE CREAM

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Silver Sulfadiazine 1% w/w

3. PHARMACEUTICAL FORM

Ointment

4. Clinical particulars

4.1 Therapeutic indications

Prophylaxis and treatment of infection in burn wounds, leg ulcers and pressure sores due to micro-organisms sensitive to this anti-infective. Conservative management of finger-tip injuries where pulp, nail loss and/or partial loss of the distal phalanx has occurred.

4.2 Contraindications

AFTERBURN Cream (silver sulfadiazine) is contraindicated in patients who are hypersensitive to silver sulfadiazine or any of the other ingredients in the preparation. Because sulfonamide therapy is known to increase the possibility of kernicterus, AFTERBURN 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.

4.3 Special warnings and precautions for use

Care should be taken to avoid spread onto non-ulcerated areas. Prolonged use of an anti-infective may result in the development of superinfection. Fungal colonisation may occur. Use with extreme caution in patients with respiratory impairment or hepatic or renal function impairment and in individuals known to have glucose-6-phosphate deficiency. Use of Silver Sulfadiazine cream USP may delay separation of burn eschar and may alter the appearance of burn wounds. One container should be reserved for use in a single patient and the remaining contents discarded after treatment is completed

4.4 Interaction with other medicinal products and other forms of interaction

As silver may inactivate enzymatic debriding agents, their concomitant use may be inappropriate. In largearea 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

4.5 Pregnancy and Lactation

Pregnancy

Pregnancy Category B. A reproductive study has been performed in rabbits at doses up to three to ten times the concentration of silver sulfadiazine in SILVADENE Cream 1% and has revealed no evidence of harm to the fetus due to silver sulfadiazine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly justified, especially in pregnant women approaching or at term.

Lactating Mothers

It is not known whether silver sulfadiazine is excreted in human milk. However, sulfonamides are known to be excreted in human milk, and all sulfonamide derivatives are known to increase the possibility of kernicterus. Because of the possibility for serious adverse reactions in nursing infants from sulfonamides, 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.

4.6 Effects on ability to drive and use machines

None known

4.7 Undesirable effects

Blood & lymphatic Tissue Disorders Common: Leukopenia Leukopenia has been reported in 3-5% of burns patients treated with Silver Sulfadiazine cream USP. 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 cream USP 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 & Urinary Disorders

Very rare: Renal failure

Skin & Subcutaneous Tissue Disorders Common: Pruritis Common: Application site rash (including eczema and contact dermatitis).

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

4.8 Overdose

Not likely to occur with normal usage

PHARMACOLOGICAL PROPERTIES

4.9 Pharmacodynamics properties

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

4.10 Pharmacokinetic properties

The silver is slowly released from the silver sulfadiazine molecule and can enter the systemic circulation. 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. Any absorbed silver may remain in the body for long periods, predominantly in liver. It is slowly excreted over time via the bile.

4.11 Preclinical safety data

No further information available

5. PHARMACEUTICAL PARTICULARS

5.1 Incompatibilities

None.

5.2 Shelf life

36 Months

5.3 Special precautions for storage

Store below 30°C. Protect from light. Do not freeze.

5.4 Nature and contents of container <and special equipment for use, administration or implantation>

30g tube.

5.5 Special precautions for disposal <and other handling>

No special requirements

6. APPLICANT/MANUFACTURER:

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