Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

FLAMAZINE Cream 1.0 % w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Silver sulfadiazine 1 % w/w.
Excipients: Contains 4% cetyl alchol and 7% w/w propylene glycol.

For a full list excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
White to off-white, oil in water, sterile homogeneous cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

FLAMAZINE cream is indicated for the prophylaxis and treatment of infection in burn wounds, leg ulcers and pressure sores due to micro-organisms sensitive to this anti-infective.

FLAMAZINE 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.

4.2 Posology and method of administration

To be applied topically.

Burns and Leg Ulcers/Pressure Sores: A layer approximately 3 to 5mm thick should be applied to the affected area using a sterile glove or spatula. The area should then be covered by an absorbent gauze dressing and support bandage where necessary. The dressing should be changed and FLAMAZINE cream applied at least every 24 hours in burn treatment, or at least three times weekly otherwise, and debridement carried out as necessary.
As Flamazine cream can cause maceration of normal skin on prolonged contact; care should be taken to avoid spread onto non-ulcerated areas.

Finger-Tip Injuries: Haemostasis of the injury should be achieved prior to the application of a 3-5mm layer of FLAMAZINE cream. A conventional finger dressing may be used. Alternatively the finger of a plastic or unsterile surgical glove can be used and fixed in place with waterproof adhesive tape. Dressings should be changed every 2-3 days.

4.3 Contraindications

As sulphonamides are known to cause kernicterus, FLAMAZINE cream should not be used in lactating women who are breast-feeding infants, on premature infants or on newborn infants during the first three months of life.
FLAMAZINE cream is also contraindicated in patients known to be hypersensitive to sulphonamides and silver sulfadiazine or other components of the preparation such as cetyl alcohol or propylene glycol.

4.4 Special warnings and precautions for use

Prolonged use of an anti-infective may result in the development of superinfection due to organisms resistant to that anti-infective. Fungal colonization may occur.

The product should only be used with extreme caution in patients with respiratory impairment or hepatic or renal function impairment.
One container should be reserved for use in a single patient and the remaining contents discarded after treatment is completed.

Caution of use is required in individuals known to have glucose-6-phosphate deficiency as sulphonamides are known to cause haemolytic anaemia in these patients.

Use of Flamazine cream may delay separation of burn eschar and may alter the appearance of burn wounds.

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 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.

4.6 Fertility, pregnancy and lactation

Studies in some animal species have shown a teratogenic effect with sulphonamides. A similar effect has not been clearly demonstrated in human beings. None the less the product should only be used during pregnancy or lactation if considered essential by the physician.

The sulphonamide concentration in breast milk is 15-35% of that in the serum. Since all sulphonamides increase the possibility of kernicterus, caution is required in nursing mothers.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

- *Blood & lymphatic Tissue Disorders*

Common: Leukopenia
Leukopenia has been reported in 3-5% of burns patients treated with Flamazine. 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 Flamazine cream 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.

4.9 Overdose

Not likely to occur with normal usage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

5.2 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 regime. 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.

5.3 Preclinical safety data

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 60
Polysorbate 80
Glycerol Monostearate
Cetyl Alcohol
Liquid Paraffin
Propylene Glycol
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

Unopened: 3 years.

Flamazine should be discarded 7 days after first opening.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container in order to protect from light.

6.5 Nature and contents of container

50 g pre-printed cylindrical white LDPE tubes fitted with white polypropylene caps.

250 g or 500 g black polypropylene jar fitted with a black polypropylene lid.

All tubes and jars are tamper evident.

Not all pack sizes may be marketed.

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

The contents of one container are for the treatment of one person.

7 MARKETING AUTHORISATION HOLDER

Smith & Nephew Pharmaceuticals Limited
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8 MARKETING AUTHORISATION NUMBER

PA0710/003/001

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