SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Flamazine Cream 1.0%w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Silver sulfadiazine 1.0%w/w

3 PHARMACEUTICAL FORM

Semi-solid oil in water emulsion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Flamazine cream is indicated for the prophylaxis and treatment of infection in burn wounds. Flamazine 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. 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 has occurred.

4.2. Posology and Method of Administration

To be applied topically.

Burns:
The burn wound should be cleaned and Flamazine cream applied over all the affected areas to a depth of 3-5mm.

This application is best achieved with a sterile gloved hand and/or sterile spatula. Where necessary, the cream should be re-applied to any area from which it has been removed by patient activity.

In burns, Flamazine cream should be re-applied at least every 24 hours, or more frequently if the volume of exudate is large.

Hand burns:

Flamazine cream can be applied to the burn and the whole hand enclosed in a clear plastic bag or glove, which is then closed at the wrist.

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 Flamazine Cream to a depth of at least 3-5mm. As Flamazine Cream can cause maceration of normal skin on prolonged contact, care should be taken to prevent spread onto non-ulcerated areas.

Application of Flamazine 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 Flamazine cream.

Flamazine 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 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. Contra-indications

As sulphonamides are known to cause kernicterus, Flamazine Cream should not be used at, or near term pregnancy, on premature infants or on newborn infants during the first months of life. Flamazine cream is also contraindicated in patients known to be hypersensitive to silver sulphadiazine or to other components of the preparation such as cetyl alcohol or propylene glycol

4.4. Special Warnings and Precautions for Use

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

4.5. Interactions with other Medicaments and other forms of Interaction

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

In large-area burns where serum sulphadiazine 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 Pregnancy and Lactation

For Flamazine 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, Flamazine cream 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

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 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

4.9. Overdose

Not likely to occur with normal usage

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Silver Sulphadiazine 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 woundds and/or after prolonged application, systemic absorption of silver can occur causing clinical argyria. The sulphadiazine 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. Sulphadiazine is excreted in the urine.

5.3. Preclinical Safety Data

None Stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

In addition to the active ingredient, silver sulphadiazine, Flamazine contains:
Polysorbate 60 Ph. Eur
Polysorbate 80 Ph. Eur
Glycerol Monostearate Ph. Eur
Cetyl Alcohol Ph. Eur
Liquid Paraffin Ph. Eur
Propylene Glycol Ph. Eur
Purified Water Ph. Eur

6.2. Incompatibilities

None Known.

6.3. Shelf Life

36 Months from date of manufacture.

6.4. Special Precautions for Storage

Flamazine should be stored below 25°C. Protect from light. The contents of one container are for the treatment of one person. 250g and 500g pots should be discarded 24 hours after opening. Tubes of Flamazine should be discarded 7 days after opening.

6.5. Nature and Contents of Container

15g, 20g, 30g or 50g pre-printed cylindrical polyethylene tubes fitted with polyethylene caps.

250g or 500g black polypropylene pot fitted with a black polyethylene or polypropylene lid.

All tubes and pots are tamper evident.

6.6. Instruction for Use/Handling

None.

7. Marketing Authorisation Holder
Smith & Nephew Pharmaceuticals Ltd,
Hessle Road, Hull,
HU3 2BN

8 MARKETING AUTHORISATION NUMBER(S)

PL 13374/0006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30 December 1993

10 DATE OF REVISION OF THE TEXT

04/12/2015