SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

FLAMAZINE Cream 1.0%w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains silver sulfadiazine 1.0%w/w.
Excipients with known effect: Contains 4% w/w cetyl alcohol and 7% w/w propylene glycol.

For a full list excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream.
White to off-white cream (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

Posology

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.

Paediatric population

FLAMAZINE Cream is contraindicated in children aged to three months (see section 4.3).

Method of administration

To be applied topically.

4.3 Contraindications

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 sulphonamides and silver sulfadiazine or to other components of the preparation such as cetyl alcohol or propylene glycol.

4.4 Special warnings and precautions for use

Life-threatening cutaneous reactions (Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)) have been reported with the use of silver sulfadiazine. Patients should be advised of the signs and symptoms and monitored closely for skin reactions. The highest risk for occurrence of SJS or TEN is within the first weeks of treatment.
If symptoms or signs of SJS or TEN (e.g. progressive skin rash often with blisters or mucosal lesions) are present, silver sulfadiazine treatment should be discontinued. The best results in managing SJS and TEN come from early diagnosis and immediate discontinuation of any suspect drug. Early withdrawal is associated with a better prognosis.
If the patient has developed SJS or TEN with the use of silver sulfadiazine, silver sulfadiazine must not be re-started in this patient at any time.

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 Interaction with other medicinal products and other forms of interaction

As silver may inactivate enzymatic debriding agents, 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

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 sulfadiazine 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

FLAMAZINE Cream has no effects on the ability to drive and use machines.

4.8 Undesirable effects

Adverse drug reactions were identified for silver sulfadiazine from clinical trials and post-marketing environment. They are listed by class and frequency. Frequencies are defined as follows:

Very common	(≥1/10)
Common	(≥1/100 to <1/10)
Uncommon	(≥1/1 000 to <1/100)
Rare	(≥1/10 000 to <1/1 000)
Very rare	(<1/10 000)
not known	(cannot be estimated from the available data)

- ***Blood and Lymphatic System Disorders***

  Common: Leukopenia

  Leukopenia has been reported in 3-5% of burns patients treated with FLAMAZINE Cream. 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 and Administration Site Conditions***

  Common: Application site burning

- ***Renal and Urinary Disorders***

  Very rare: Renal failure

- ***Skin and Subcutaneous Tissue Disorders***

  Common: Pruritis

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

  Rare: Argyria

  Very rare: Severe cutaneous adverse reactions (SCARs) Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) (see section 4.4).

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 medicinalproduct. Healthcare professionals are asked to report any suspected adverse reactions.

United Kingdom (Northern Ireland)
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

Not likely to occur with normal usage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: silver sulfadiazine, ATC code: D06BA01

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

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

Not applicable.

6.3 Shelf life

Unopened: 3 years.

250g and 500g pots should be discarded 24 hours after opening.
Tubes of FLAMAZINE Cream should be discarded 7 days after opening.

6.4 Special precautions for storage

FLAMAZINE Cream should be stored below 25°C. Protect from light.
The contents of one container are for the treatment of one person.

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.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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

Date of first authorisation: 30 December 1993

10 DATE OF REVISION OF THE TEXT

02/07/2023