Summary of Product Characteristics

DERMAFLAME CREAM

1. NAME OF THE MEDICINAL PRODUCT

DERMAFLAME CREAM

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition

silver sulfadiazine usp,1% w/w , Chlorhexidine gluconate solution usp 0.2 % w/w, Chlorocresol 0.1 % w/w

Excipients with known effect:
Propylene glycol, cetostearyl alcohol.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White to slightly grey-white or pinkish-white.

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

Dermaflame 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 **Dermaflame** 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, Silverol 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.

Dermaflame 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.

these medicines, it is recommended that blood levels should be monitored as their effect can be potentiated.

4.6 Fertility, pregnancy and breastfeeding

For Dermaflame no clinical data on exposed pregnancies are available, although animal studies have not shown any hazard.

Since all sulphonamides increase the risk of kernicterus, **dermaflame** should not be used in pregnant females at term and causion 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 **dermaflame** 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 **DERMAFLAME 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 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 absorbsion 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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

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

dermaflame 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, 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 Silverol 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.

Treatment with **dermaflame** 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, Silverol Cream should not be used at, or near term of pregnancy, on premature infants or on newborn infants during the first months of life.

dermaflame 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

Dermflame 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 **Dermflame** may delay separation of burn eschar and may alter the appearance of the burn wounds.

Important information on excipients

This medicine contains 7 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 imappropriate.

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

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 regime. Sulfadiazine is excreted in the urine.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mineral oil (paraffin liquid), propylene glycol, cetostearyl alcohol, glycerol monostearate, glyceryl monostearate self emulsifying, polysorbate 60, polysorbate 80 , methylparaben (methyl parahydroxybenzoate), purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store in a dark place below 25°C.

6.5 Nature and contents of container

Tubes containing 30g cream

7 License Holder and Manufacturer

8 Registration Number

The leaflet was revised in January 2022 according to Ministry of Health guidelines.