1. Name of the Medicinal Product

Silvex Cream

2. Qualitative and quantitative composition

Each 100 g of Silvex cream contains 1 g of silver sulfadiazine.

For a full of excipients see section 6.1.

3. Pharmaceutical Form

Topical cream

4. Clinical Particulars

4.1 Therapeutic Indication

Silvex cream is indicated for the prophylaxis and treatment of infection in burn wounds. Silvex 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. Silvex cream is also indicated for the conservative management of fingertip 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 Silvex cream applied over all the affected areas to a depth of 3-5 mm. 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, Silvex cream should be re-applied at least every 24 hours, or more frequently if the volume of exudate is large.

Hand burns:

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

Application of Silvex 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 Silvex cream. Silvex 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 3-5 mm layer of Silvex 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 Contraindication

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

4.4 Special warning and precautions for use

Silvex 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 sulfonamides and in individuals known to have glucose-6-phosphate dehydrogenase deficiency. Use of Silvex 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, 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 hypoglycemic 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 Silvex cream no clinical data on exposed pregnancies are available, although animal studies have not shown any hazard. Since all sulfonamides increase the risk of kernicterus, Silvex 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

None known

4.8 Undesirable effects

- ***Blood & lymphatic Tissue Disorders***

  Common: Leukopenia

  Leukopenia has been reported in 3-5% of burns patients treated with silver sulfadiazine. 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 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, Application site rash (including eczema and contact dermatitis)

  Rare: Argyria

4.9 Overdose

None known

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

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 known

6. Pharmaceutical Particulars

6.1 List of excipients

Propylene glycol

Cetyl alcohol

Polysorbate 60

Methylparaben

Propylparaben

Arachis oil hydrogenated

Citric acid anhydrous

Trisodium citrate dihydrate

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30 °C and protect from light

Do not refrigerate or freeze.

6.5 Nature and contents of container

25 g aluminium tube

250 g and 500 g black plastic jar

7. Marketing Authorization Holder

7.1 Distributed by

R.X. Company Ltd.

93/90 Soi Prachanukul 2, Rachadapisek Rd, Bangsue, Bangkok 10800, Thailand.

Tel. +66 2910-0950-60 http://www.rx.co.th

7.2 Manufactured by

R.X. Manufacturing Co., Ltd.

76 Moo 10, Narapirom, Banglane, Nakornphathom 73130, Thailand.

8. Marketing Authorization Numbers

9. Date of First Authorization/Renewal of the Authorization

10. Date of revision of the text: 03/07/2020