

pharmaniaga[®]

IDAMAN SILVER SULFADIAZINE CREAM 1% W/W

PRODUCT DESCRIPTION

A smooth, soft, white homogenous cream.

COMPOSITION

Each gram contains:

Silver Sulfadiazine: 10 mg

Preservative: Chlorocresol: 1 mg

PHARMACODYNAMICS

Mechanism of action

Silver sulfadiazine is a sulfonamide and has broad antimicrobial activity against both Gram-positive and Gram-negative organisms.

Silver sulfadiazine acts on the cell membrane and cell wall. Unlike sulfadiazine or other sulfonamides, the antibacterial action of the silver salt of sulfadiazine does not appear to depend on inhibition of folic acid synthesis. Its action is not antagonised by p-aminobenzoic acid.

Silver sulfadiazine has broad antimicrobial activity against both Gram-positive and Gram-negative organisms including *Pseudomonas aeruginosa*, some yeasts and fungi. It has also been reported to be active in vitro against herpes virus and *Treponema pallidum*. Sulfonamides act by interfering with the synthesis of nucleic acids in sensitive micro-organisms by blocking the conversion of p-aminobenzoic acid to the co-enzyme dihydrofolic acid. Silver sulfadiazine has a bactericidal action; in contrast to sulfadiazine, the silver salt acts primarily on the cell membrane and cell wall and its action is not antagonised by p-aminobenzoic acid.

Resistance to silver sulfadiazine has been reported and may develop during therapy.

PHARMACOKINETICS

Silver sulfadiazine is slowly metabolised in contact with wound exudates. Up to about 10% of the sulfadiazine may be absorbed; concentrations in blood of 10 to 20 µg/mL have been reported although higher concentrations may be achieved when extensive areas of the body are treated.

Some silver may be absorbed.

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.

INDICATIONS

For prevention and treatment of infection in burn wounds. It has also been used as an aid to the short-term treatment in other skin conditions such as leg ulcers where infections may prevent healing and as an aid to prophylaxis of infection in skin grafting.

RECOMMENDED DOSAGE

Idaman Silver Sulfadiazine Cream 1% w/w is applied topically to cleansed burned/affected areas once or twice daily approximately 1.5mm thick, using a sterile-gloved hand or spatula. Dressing is usually not required but it can be used. It should be applied to the burn wound/affected area as long as there is a possibility of infection or prescribed by the physician.

Whenever necessary, the cream should be re-applied to any areas from which it has been removed.

Treatment with Idaman Silver Sulfadiazine Cream 1% w/w should be continued until satisfactory healing has occurred, or until the burn site is ready for grafting.

ROUTE OF ADMINISTRATION

Topical

CONTRAINDICATIONS

As sulfonamides are known to cause kernicterus, Idaman Silver Sulfadiazine Cream 1% w/w should not be used at, or near-term pregnancy, on premature infants or on newborn infants during the first months of life. Idaman Silver Sulfadiazine Cream 1% w/w is also contraindicated in patients known to be hypersensitive to silver sulfadiazine or to other components of the preparation such as cetyl alcohol.

WARNINGS AND PRECAUTIONS

Identified Precautions

Transient leucopenia has occurred although its association with application of has not been confirmed. Nevertheless, regular blood counts are advisable in patients on long-term treatment.

Patients should be watched carefully for sensitivity, especially if there are known reactions to sulfonamides.

Local reactions have been reported in patients treated with silver sulfadiazine; the separation of the eschar may be delayed and fungal invasion of the wound may occur.

In patients with extensive burns, serum sulfonamide concentrations and renal function should be monitored and urine examined for sulfonamide crystals.

The use of Idaman Silver Sulfadiazine Cream 1% w/w in some cases of glucose-6-phosphate dehydrogenase-deficient patients may be hazardous as haemolysis may occur.

During treatment of burns over a large body area, significant amounts of silver sulfadiazine are systemically absorbed. Therefore, it is possible that any adverse reactions associated with sulfonamides may occur.

Use in hepatic impairment/renal impairment

Idaman Silver Sulfadiazine Cream 1% w/w should be used with caution in patients with impaired renal or hepatic function.

Sensitivity has been shown to occur but the incidence is lower than with other sulfonamides.

Use in the elderly

Of the total number of subjects in clinical studies of Silver sulfadiazine cream, seven percent were 65 years of age and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Pediatric use

Idaman Silver Sulfadiazine Cream 1% w/w should not be used in premature infants or in newborn infants in the first months of life.

Effects on laboratory tests

In the treatment of burn wounds involving extensive areas of the body, the serum sulfonamide derivative concentrations may approach adult therapeutic levels (8 mg% to 12 mg%). Therefore, in these patients it would be advisable to monitor serum sulfonamide concentrations. Renal function should be carefully monitored and the urine should be checked for sulfonamide crystals.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Unlikely to impair a patient's ability to drive or use machinery.

INTERACTIONS WITH OTHER MEDICAMENTS

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.

Cimetidine: in patients with large area burns, it has been reported that coadministration of cimetidine may increase the incidence of leukopenia.

Sulfonamide may alter the effect of oral anticoagulants, methotrexate, and cyclosporine. There are isolated reports that sulfonamide may also interfere with the effectiveness of hormonal contraceptive.

PREGNANCY AND LACTATION

Effects on Fertility

No data were available from studies in animals following topical administration of silver sulfadiazine.

No treatment-related effects on male or female fertility were documented following subcutaneous administration of silver sulfadiazine to rats at doses up to 500mg/kg/day for two (females) or ten (males) weeks prior to mating.

Use in pregnancy – Pregnancy Category C

Sulfonamides may cause kernicterus in babies during the first month of life by displacing bilirubin from plasma albumin. Sulfonamides should therefore be avoided as far as possible during the last month of pregnancy. Fetal findings (abdominal hernia and laevorotation of the heart) occurred in low incidence in rats at subcutaneous doses of $\geq 250\text{mg/kg/day}$ during early embryonic development and organogenesis. The significance of these findings for clinical topical administration is unknown.

Use in lactation.

Idaman Silver Sulfadiazine Cream 1% w/w should be used with caution in breast-feeding mothers. Systemically, sulfadiazine can be excreted in breast milk although at concentrations 15 -35% of those found in serum.

SIDE EFFECTS

Blood & Lymphatic Tissue Disorders

Common: Leukopenia

Leukopenia has been reported in 3-5% of burns patients. 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 [product name] 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 suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product

SYMPTOMS AND TREATMENT OF OVERDOSE

Not likely to occur with normal usage.

In extensively burned patients or in patients suspected of showing symptoms of excessive absorption, it is important to optimally maintain fluid balance, not only to prevent dehydration but also to avoid the possibility of renal failure.

If renal function is normal, fluids should be administered to maintain high urine output and assist in the rapid elimination of the drug.

STORAGE CONDITION

Store below 30°C. Protect from light.

SHELF LIFE

Product should not be used beyond the expiry date imprinted on the product packaging.

PACK SIZE

HDPE container of 500g

REGISTRATION NUMBER

MAL25036010AZ

**CONTROLLED MEDICINE
UBAT TERKAWAL**

**KEEP MEDICINES OUT OF REACH OF CHILDREN
JAUHI UBAT-UBATAN DARI KANAK-KANAK**

For further information, please consult your doctor or your pharmacist.

Revision Number : 01

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**Product Registration Holder and Manufacturer
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