DERMAZINE®
SILVER SULFADIAZINE USP
1% CREAM

DESCRIPTION
A white non-greasy, non- gritty Cream.

COMPOSITION:
Each gram contains 10 mg Silver Sulfadiazine USP.

PHARMACOLOGY
Silver sulfadiazine acts upon the cell membrane and cell wall. Unlike sulfadiazine and other sulfonamides, the antibacterial action of the silver salt of sulfadiazine does not appear to depend on inhibition of bacterial folic acid synthesis; silver sulfadiazine's activity is not competitively inhibited by aminobenzoic acid (p-aminobenzoic acid). Silver Sulfadiazine has antibacterial activity especially against Pseudomonas aeruginosa. As silver sulfadiazine is relatively insoluble it reacts very slowly with the chloride and protein components of tissue exudates to form silver chloride, silver protein complexes and sodium sulfadiazine. Sulfadiazine is now available to exert its bacteriostatic effect and is very slowly absorbed. The mechanisms for silver ion release are complex, but silver chloride is very slightly soluble and slowly releases silver ions, which are then free to exert their bactericidal effect. These silver ions are thought to be reversibly adsorbed by bacterial cells by association with SH groups or histidine residues in the bacterial protein of the transport system across the cell wall.

$$NaCl + AgSd \dashrightarrow AgCl + NaSd$$
$$AgCl \rightleftharpoons Ag^{+} + Cl^{-}$$
$$2AgCl + 2NaCl \rightleftharpoons 2Na^{+} + 2AgCl_2$$

Thus silver sulfadiazine acts as a sustained release depot of silver and sulfadiazine at the wound surface.
The slow liberation of silver does not cause the rapid and extensive depletion of chloride ion experienced when silver nitrate solutions are used, and thus electrolyte disturbances are minimized.

PHARMACOKINETICS
Silver sulfadiazine itself does not appear to be absorbed. When in contact with body tissues and fluids, silver sulfadiazine slowly reacts with sodium chloride, sulfhydryl groups, and protein, resulting in the release of sulfadiazine. Sulfadiazine may be systemically absorbed from the site of application, particularly when silver sulfadiazine is applied to second-degree burns. When the drug is applied to extensive burns, serum sulfadiazine concentrations of up to 12 mg/dL have been reported. In one study, patients who were treated with 5–10 g of silver sulfadiazine daily applied as a 1% cream were found to have blood sulfadiazine concentrations of 1–2 mg/dL; 100–200 mg of sulfadiazine was excreted in urine within 24 hours following application of the cream.

INDICATIONS
Prevention and treatment of Infection in cuts, wounds, Burns and bed sores being particularly effective against Gram-negative organisms such as Pseudomonas aeruginosa and pyocyanea, the most common cause of burn wound infection.

CONTRA-INDICATIONS:
Patients with a known sensitivity to Sulfonamides. Because of the possibility of kernicterus it should not be used by pregnant women near term or by new-born infants. Silver sulfadiazine should be used with care in the presence of hepatic or renal impairment, or when porphyria is suspected.

DOSAGE AND DIRECTIONS FOR USE:
For external use only
Silver sulfadiazine cream should be applied to a thickness of 3 to 5 mm daily with a sterile gloved hand and may, if desired, be covered by a thin gauze dressing. Treatment should be continued till the risk of infection has passed. One container should be reserved for one patient and any remaining cream should be discarded on completion of treatment.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Sensitivity reactions have been reported, and patients should be watched carefully especially if there is a known reaction to sulfonamides. Separation of the eschar may be delayed. Local skin sensitivity may occur especially when exposed to sunlight. The safety of silver sulfadiazine in pregnancy has not been established. While little silver is absorbed, the plasma concentration of sulfadiazine may approach therapeutic levels, and particular attention must be paid to adequate fluid intake and acid-base balances.
A fall in white blood cell count has been demonstrated but it is not thought to be associated with the treatments used and probably reflects the condition of the burned patient.

PRESENTATION
Plastic jars of 100, 250 gm.
Collapsible tubes of 15gm, 50gm

STORAGE
Store in a dry place below 30°C, protected from light.
Keep out of reach of children

Manufactured By:

DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka
P. O. Box 16633 00620, Nairobi, Kenya.

Ref: DER/LL/08/20 Date of issue: August 2020