

**Dermazine® Plus**  
**Silver Sulfadiazine**  
**1% W/W and Chlorhexidine Gluconate 0.20% W/W Cream**

**DESCRIPTION**

A white non-greasy, non-gritty Cream

**COMPOSITION**

Each gram contains 10 mg (1.0%w/w) Silver Sulfadiazine

Each gram contains 2 mg (0.20%w/w) Chlorhexidine Gluconate.

**PHARMACOLOGICAL CLASSIFICATION**

Antibiotic cream for wounds cuts and burns.

**PHARMACOLOGY**

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.

$\text{NaCl} + \text{AgSd} \rightleftharpoons \text{AgCl} + \text{NaSd}$

$\text{AgCl} \rightleftharpoons \text{Ag}^+ + \text{Cl}^-$

$\text{AgCl} + \text{NaCl} \rightleftharpoons \text{Na}^+ + \text{AgCl}^-$

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. Chlorhexidine is a bisbiguanide antiseptic and disinfectant that is bactericidal or

bacteriostatic against a wide range of Gram-positive and Gram-negative bacteria. It is more effective against Gram-positive than

Gram-negative bacteria, and some species of *Pseudomonas* and *Proteus* have low susceptibility. It is relatively ineffective against

mycobacteria. Chlorhexidine inhibits some viruses and is active against some fungi.

Chlorhexidine is poorly absorbed from the gastrointestinal tract and skin.

Occasional percutaneous absorption of Chlorhexidine in neonates and infants has been reported.

**INDICATIONS**

This combination has an enhanced activity for the 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. The cream is also used as a barrier against bacterial hand infection.

**CONTRA-INDICATIONS**

Patients with a known sensitivity to Sulfonamides and Biguanides. 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**

The 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 and Biguanides. 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.

Skin sensitivity to Chlorhexidine has occasionally been reported.

There has been a report of cases of corneal damage due to contact with Chlorhexidine Gluconate used for pre-operative preparation of facial skin. Temporary hyposmia (reduced sense of smell) in some patient has also been reported. Severe hypersensitivity reactions including anaphylactic shock have been reported following topical applications of chlorhexidine, 1-4 and from the use of Chlorhexidine-containing lubricants for urinary catheterization or cystoscopy. Since Chlorhexidine is an irritant, it is recommended that it should not be used on the brain, meninges, middle ear, or other sensitive tissues. Contact with the eyes should be avoided.

**PRESENTATION**

Tube of 15 gm in a unit carton.

**STORAGE**

Dermazine should be stored below 30°C, in a dry and dark place.

Keep out of reach of children.

**Manufactured By:**



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