



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
SILVER SULPHADIAZINE 1% w/w CREAM

Silver Sulphadiazine

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What Silver Sulphadiazine Cream is and what it is used for
2. Before you use Silver Sulphadiazine Cream
3. How to use Silver Sulphadiazine Cream
4. Possible side effects
5. How to store Silver Sulphadiazine Cream
6. Further information

1. WHAT SILVER SULPHADIAZINE CREAM IS AND WHAT IT IS USED FOR

Silver Sulphadiazine belongs to a group of medicines called antibacterial which are used for the prophylaxis and treatment of infection in burn wounds.

2. BEFORE YOU USE SILVER SULPHADIAZINE CREAM

Do not use Silver Sulphadiazine Cream

- If you are allergic (hypersensitive) to the active substance(s) or any of the other ingredients of Silver Sulphadiazine Cream.
- For preterm infants or newborns under 2 months.
- If you are pregnant and approaching term.

Warnings and Precautions

- Caution of use is required in individuals known to have Glucose-6-phosphate dehydrogenase deficiency; hemolysis may occur.
- Hepatic or renal impairment; accumulation may occur; discontinuation may be necessary blood dyscrasias (e.g. agranulocytosis, aplastic anaemia, thrombocytopenia, leukopenia, hemolytic anemia) may occur.
- CNS reactions may occur.
- Cross-sensitivity with other sulfonamides may occur; if allergic reactions occur, consider potential hazards of continuing therapy.
- Cutaneous reactions, life-threatening (e.g. Stevens-Johnson syndrome, Toxic Epidermal Necrolysis [TEN], exfoliative dermatitis), may occur.
- Fungal proliferation, in or below the eschar, may occur.
- Gastrointestinal reactions may occur.
- Hepatitis or hepatocellular necrosis may occur.
- Toxic nephrosis may occur.
- Discontinue treatment with this drug immediately if skin rash or any sign of adverse reaction occurs.
- Fatalities associated with the administration of sulphonamides and trimethoprim, either alone or in combination, have occurred due to severe reactions, including Steven-Johnson syndrome, toxic epidermal necrolysis and other reactions. The drug should be discontinued at the first appearance of skin rash or any sign of adverse reaction.
- Urinalyses may be required prior to and periodically during treatment to detect crystalluria and/or urinary calculi formation in patients on long-term or high-dose therapy and in patients with impaired renal function.
- If allergic reactions or hepatic or renal function impairment with decreased elimination occurs, discontinuation of therapy with the medication should be considered.

Effects on the ability to drive and use machines

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

Interactions with Other Medicaments

Concurrent application of papain and silver salt-containing formulations such as silver sulfadiazine may result in the inactivation of the enzymatic debriding action of papain.

Pregnancy and breast-feeding

Ask your health care provider for advice before taking any medicine.

3. HOW TO USE SULPHADIAZINE CREAM

Silver sulfadiazine 1% cream should be applied with a sterile, gloved hand to the burn surface once or twice daily to a thickness of approximately 1/16th inch (1.5mm), and continued until satisfactory healing occurs, until the burn site is ready for grafting. Silver sulfadiazine should be applied more frequently to burn areas which might allow easier removal of the cream by movement of the patient. Dressings can be applied over the cream, but this is usually not necessary.

Renal Failure: No specific dosage adjustment of silver sulfadiazine is necessary. Although silver is not readily absorbed, sulfadiazine can be absorbed in significant quantities following prolonged treatment of extensive burns, and measurement of sulfadiazine levels may be indicated in patients with impaired renal function

Hepatic Insufficiency: No specific dosage adjustment of silver sulfadiazine is necessary. However, large amounts of sulfadiazine may be absorbed following prolonged treatment of extensive burns, and serum sulfonamide levels should be monitored during prolonged use of the drug in patients with impaired hepatic function.

Use in children

Safety and effectiveness not established in children

Mode of Administration

Topical.

Contact with the eyes should be avoided. In case of accidental contact with the eyes, rinse the eyes thoroughly with running water.

If you use more Silver Sulphadiazine Cream than you should

Management of over dosage is usually symptomatic and supportive.

If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Silver Sulphadiazine Cream can cause side effects, although not everybody gets them.

- Dermatologic: Local reactions such as burning, pruritus, rash, skin irritation, skin necrosis, erythema multiforme and skin discoloration may occur.
- Hematologic: Disorder of hematopoietic structure (rare), Leukopenia (rare)
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

Reporting of side effects

If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Fidson Healthcare Plc. By reporting side effects, you can help provide more information on the safety of this medicine.

Title:	Insert Specification Sheet for Silver Sulphadiazine Cream				
Paper type:	75gsm	Packaging tracking code:	PMN0545-0620-01	Font Colour:	Pantone Black [Monocoloured]
Dimension:	L – 148mm; H 210mm	Font type & size:	Arial: 5pt [Font size may be adjusted proportion to fit paper dimension]		

	Prepared By:		Approved by:
Signature			
Date	08.07.2020	08-07-2020	08-07-2020
Designation	AMRA	HoM	HQRA



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5. HOW TO STORE SILVER SULPHADIAZINE CREAM

Keep all medicines out of the reach of children.

Do not use this medicine after the expiry date which is stated on the carton after 'Exp. Date' used for expiry date. The expiry date refers to the last day of that month.

Store below 30°C, in a dry place.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Silver Sulphadiazine Cream contains:

The active pharmaceutical ingredient is Silver Sulphadiazine.

What Silver Sulphadiazine Cream looks like and contents of the pack:


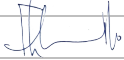

25g cream in a tube, placed in a carton with insert.

Supplier and Manufacturer

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Sango Ota, Ogun State
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customercare@fidson.com

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