



PACK INSERT PACKAGING DEVELOPMENT

Product Name : FLOVIDIAZINE Cream		Date : 18/12/2019	
Size : L-90mm x H-135mm	Size after Folding : L-90 mm x H-23 mm		Pack : 20 gm Cream Pack Insert
Grammage : 57gsm ±5% Map - Litho paper	Country : Philippines - Order		ERP Code : PPIPHF012
Colour : Black (Single Colour)		Proof No. :	
Regulatory	Packaging Develop.	QA	Prepared by Artist
Sign:			
Date:			

Black

NOTE: Do not use any Symbol

Check Points	Reg.	Pkg. Dev.	QA	A/W
Brand Name				
Generic Name				
Label Claim				
Dosage				
Storage Condition				
Mfg. Lic. No.				
Address,				
Overprinting Area				
ERP Code				
Dimensions				
Specifications				
Barcode				
Warnings				
Reg. No.				
Colour				



SILVER SULFADIAZINE

FLOVIDIAZINE

10 mg/g 1% w/w Cream

ANTIBACTERIAL (SULFONAMIDE)



FOR EXTERNAL USE ONLY

FORMULATION:

Silver Sulfadiazine..... 10 mg/g (1% w/w)
Methyl Hydroxybenzoate..... 2 mg/g (0.2% w/w)
Propyl Hydroxybenzoate..... 1 mg/g (0.1% w/w)

PRODUCT DESCRIPTION:

White homogenous cream

PHARMACODYNAMICS:

Pharmacological action:

Silver Sulfadiazine has broad antimicrobial activity against Gram-positive and Gram-negative bacteria including *Pseudomonas aeruginosa* and some yeasts and fungi. Silver Sulfadiazine has bactericidal action in contrast to sulfadiazine, the silver salt acts primarily on the cell membrane and cell wall and its action is not antagonized by p-aminobenzoic acid.

PHARMACOKINETICS:

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

INDICATIONS:

Silver Sulfadiazine cream is indicated for the prevention and treatment of infection in severe burns. It is also been used in other skin conditions, such as leg ulcers, where infection may prevent healing and for the prophylaxis of infection in skin grafting. It has also been applied to the eyes in the treatment of superficial Aspergillus infections.

DOSAGE AND ADMINISTRATION:

Silver Sulfadiazine cream to be applied daily in a layer approximately 3-5 mm thick with a sterile gloved hand or spatula. The wound may be dressed or left open. One container of Silver Sulfadiazine should be reserved for one patient and any remaining cream should be discarded on completion of treatment.

CONTRAINDICATIONS:

Hypersensitivity to Silver Sulfadiazine or any of the excipients in this product.

WARNINGS AND PRECAUTIONS:

Patients should be watched carefully for sensitivity reactions; the separation of the scar may be delayed and fungal invasion of the wound may occur. Appreciable amounts of sulfadiazine may be absorbed systemically to produce therapeutic blood levels and particular attention must be paid to adequate fluid intake and acid base balances. Discontinue use if sensitization or irritation occurs.

DRUG INTERACTIONS:

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.

PREGNANCY AND LACTATION:

Pregnancy: Silver Sulfadiazine should not be used in pregnant women unless the potential benefit justifies the potential risk to the foetus.

Lactation: It is not known whether topically applied Silver Sulfadiazine is secreted in breast milk. Caution should be exercised when Silver Sulfadiazine cream is prescribed to nursing women.

ADVERSE DRUG REACTIONS:

Local pain or irritation are uncommon; the separation of the scar may be delayed and fungal invasion of the wound may occur. Systemic absorption of silver, resulting in argyria, can occur when Silver Sulfadiazine is applied to large area wounds or over prolonged periods.

OVERDOSE AND TREATMENT:

Not likely to occur with normal usage.

STORAGE CONDITION:

Store at temperatures not exceeding 30° C.

CAUTION:

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov/ph.

Seek medical attention immediately at the first sign of any adverse drug reaction.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Carefully read the accompanying instructions before use.

AVAILABILITY:

Aluminum Tube x 20 g (Box of 1's)

SHELF LIFE: 3 years.

DRP-3701-03

Date of First Authorization: September 18, 2018

Date of Revision of Package Insert: December 02, 2019

Manufactured by:

AGIO PHARMACEUTICALS LTD.

T-82, M.I.D.C. Bhosari, Pune 411026,

Maharashtra State, India

Imported by:

AMBICA INTERNATIONAL CORPORATION

No. 9 Amsterdam Extension, Merville Park Subd.,

Parañaque, Metro Manila

Distributed by:

GUIMHEALTH PHARMACEUTICAL DISTRIBUTOR AND DRUGSTORE

Robinson's Car Park Bldg., Robinsons Place,

J. de Leon St., Iloilo City, Iloilo

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