



AGOG Pharma Ltd.



(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gaurai-pada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

LEAFLET

AGOBURN

(Silver Sulfadiazine Cream USP 1% W/W)

COMPOSITION :

Silver Sulfadiazine USP.....1% w/w
Cream base..... q.s.

PHARMACOLOGICAL ACTION :

Silver sulfadiazine has broad antimicrobial activity. It is bactericidal for many gram-negative and gram-positive bacteria as well as being effective against yeast. Silver sulfadiazine acts only on the cell wall to produce its bactericidal effect. Silver sulfadiazine is not a carbonic anhydrase inhibitor and may be useful in situations where such agents are contraindicated.

INDICATIONS :

- Cools at once
- Rapidly relieves pain
- Prevents and fight infections in burns, wounds, cuts and bacterial infections of the skin.

DIRECTION FOR USE :

- Apply Agoburn gently over cuts and scratches.
- Apply on wounds, sores, ulcers, freely on gauze and apply dressing to injured parts.
- Apply Agoburn on burns gently.
- Agoburn cools at once, soothes, rapidly relieves pain and heals quickly.

CONTRAINDICATIONS :

Silver Sulfadiazine Cream is contraindicated in patients who are hypersensitive to silver sulfadiazine. Because sulfonamide therapy is known to increase the possibility of kernicterus.

WARNING :

There is a potential cross-sensitivity between silver sulfadiazine and other sulfonamides. If allergic reactions attributable to treatment with silver sulfadiazine occur, continuation of therapy must be weighed against the potential hazards of the particular allergic reaction. Fungal proliferation in and below the eschar may occur. The use of Silver Sulfadiazine Cream in some cases of glucose-6-phosphate dehydrogenase-deficient individuals may be hazardous, as haemolysis may occur.

PREGNANCY :

Silver Sulfadiazine Cream should not be used on pregnant women approaching or at term, on premature infants, or on newborn infants during the first 2 months of life.

NURSING MOTHER :

It is not known whether Silver Sulfadiazine Cream is excreted in human milk. However, sulfonamides are known to be excreted in human milk and all sulfonamides derivatives are known to increase the possibility of kernicterus. Because of the potential for serious adverse reactions in nursing infants from sulfonamides, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

ADVERSE REACTIONS :

Several cases of transient leucopenia have been reported in patients receiving silver sulfadiazine therapy. Leucopenia associated with silver sulfadiazine administration is primarily characterized by decreased neutrophil count. Maximal white blood cell depression occurs within two to four days of initiation of therapy. Rebound to normal leukocyte levels follows onset within two to three days. Recovery is not influenced by continuation of silver sulfadiazine therapy.

Other infrequently occurring events include skin necrosis, erythema multiforme, skin discoloration, burning sensation, rashes, and interstitial nephritis.

CAUTION :

- For external use only.
- Wash hands after use.
- Avoid use on broken skin, the eyes, nose or lips.

STORAGE :

Store under normal storage conditions (15°C to 30°C).
Protect from light.

Keep all medicines out of reach of children.

PRESENTATION :

15 gm tube in a carton.



Manufactured in India by :

AGOG PHARMA LTD.

Plot No. 33, Sector II, The Vasai Taluka Indl. Co-op. Estate Ltd., Vasai (E), Dist. Thane. INDIA.

W 83 mm X H 127 mm 15 / 5 / 2013

Front

Back



1.5.3 Patient Information Leaflet (PIL)

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