

PRESCRIBING INFORMATION

Sofra-Tulle

(Framycetin sulphate B.P. 1%)

Topical Antibiotic



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Date of Preparation:
July 02, 2003

Date of Revision:
August 15, 2012

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NAME OF DRUG

SOFRA-TULLE

(Framycetin sulfate B.P. 1%)

THERAPEUTIC CLASSIFICATION

Topical Antibiotic

CLINICAL PHARMACOLOGY

Framycetin, a broad spectrum aminoglycoside antibiotic, is usually bactericidal in action. Although the exact mechanism of action has not been fully elucidated, the drug appears to inhibit protein synthesis in susceptible bacteria by binding to ribosomal subunits. In general, framycetin is active against many aerobic gram-negative bacteria and some aerobic gram-positive bacteria, namely staphylococci including *S. aureus*. The drug is inactive against fungi, viruses, and most anaerobic bacteria.

INDICATIONS AND CLINICAL USE

Treatment of infected or potentially infected burns, wounds, ulcers and graft sites.

CONTRAINDICATIONS

Known allergy to lanolin or framycetin. Organisms resistant to framycetin.

PRECAUTIONS

In most cases, where small areas are covered with the tulle, absorption of the antibiotic is so slight that it can be discounted. However, where a very large body surface is involved (e.g., 30% or more body surface area), the possibility of eventual toxicity and nephrotoxicity must be considered. Prolonged use of antibiotics may result in the overgrowth of nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs. Cross sensitization may occur among the group of Streptomyces derived antibiotics (neomycin, paromomycin, kanamycin) of which framycetin is a member, but this is not invariable.

DOSAGE AND ADMINISTRATION

A single layer to be applied directly to the wound and covered with an appropriate dressing. If exudative, dressings should be changed at least daily. In case of leg ulcers cut dressing accurately to size of ulcer to decrease the risk of sensitization and to avoid contact with surrounding healthy skin.

AVAILABILITY AND DOSAGE FORMS

Dosage forms :

A lightweight, lano-paraffin (anhydrous lanolin 9.95%) gauze dressing impregnated with 1% framycetin sulfate BP. Available in 2 sizes: 10 cm by 10 cm sterile single units, flow wrapped packages of 10 and 50; 10 cm by 30 cm sterile single units, cartons of 10.

Storage :

Store flat at temperature between 15-25°C.