

PRESCRIBING INFORMATION

Sofra-Tulle

(Framycetin sulphate B.P. 1%)

Topical Antibiotic



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Montréal, QC
Canada, H4P 2P5

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PRESCRIBING INFORMATION

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.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of SOFRA-TULLE and other antibacterial drugs, SOFRA-TULLE should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

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 totoxicity 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.

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing SOFRA-TULLE in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of resistant organisms.

Overdosage

In case of suspected drug overdose, including oral ingestion, contact your regional poison control center

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.

Patient Medication Information

SOFRA-TULLE

Framycetin sulfate B.P. 1%

Read this carefully before you start using SOFRA-TULLE. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about SOFRA-TULLE.

What is SOFRA-TULLE used for?

SOFRA-TULLE is used to treat infected burns, wounds, ulcers and graft sites.

Antibacterial drugs like SOFRA-TULLE treat only bacterial infections. They do not treat viral infections.

How does SOFRA-TULLE work?

SOFRA-TULLE contains an antibiotic. It works by killing or stopping the growth of bacteria that cause disease.

What are the ingredients in SOFRA-TULLE?

Medicinal ingredient: framycetin.

Non-medicinal ingredients: lano-paraffin.

SOFRA-TULLE comes in the following dosage forms:

Gauze dressing available in 2 sizes:

- 10 cm by 10 cm sterile single units, or flow wrapped packages of 10 and 50; and 10 cm by 30 cm sterile single units or cartons of 10.

Do not use SOFRA-TULLE if you:

- are allergic or you have a sensitivity to framycetin or any of the other ingredients listed above.
- have an infection that is resistant to SOFRA-TULLE.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you use SOFRA-TULLE. Talk about any health conditions or problems you may have, including if you:

- are allergic to any other antibiotic

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to use SOFRA-TULLE:

- Follow all instructions given to you by your healthcare professional.
- Although you may feel better early in treatment, SOFRA-TULLE should be used exactly as directed.
- Misuse or overuse of SOFRA-TULLE could lead to the growth of bacteria that will not be killed by SOFRA-TULLE (resistance). This means that SOFRA-TULLE may not work for you in the future.
- Do not share your medicine.
- Apply a single layer directly to the wound and cover with an appropriate dressing.
- Depending on the type of wound, dressings should be changed at least daily. In case of leg ulcers cut dressing accurately to size of ulcer to avoid contact with surrounding healthy skin.

Usual dose of SOFRA-TULLE:

Your healthcare professional will decide how much and for how long you should use SOFRA-TULLE.

OVERDOSE

If you think you have used too much SOFRA-TULLE or in case of ingestion, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using SOFRA-TULLE?

These are not all the possible side effects you may feel when using SOFRA-TULLE. If you experience any side effects not listed here, contact your healthcare professional.

Rarely, a local allergic reaction can occur.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store SOFRA-TULLE flat at room temperature (15 to 25°C).

Keep out of reach and sight of children.

If you want more information about SOFRA-TULLE :

- Talk to your healthcare professional
- Find the full prescribing information that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website (www.eci2012.net), or by calling 1-800-931-3133.

This leaflet was prepared by ERFA Canada 2012 Inc.

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