

## PRESCRIBING INFORMATION

### **Pr SOFRAMYCIN® Nasal Spray**

Framycetin sulfate, gramicidin and phenylephrine hydrochloride nasal spray  
Antibiotic-Decongestant

### **Pr SOFRAMYCIN® Skin Ointment**

Framycetin sulfate and gramicidin ointment  
Antibiotic

### **Pr SOFRAMYCIN® Sterile Eye Ointment**

Framycetin sulfate ophthalmic ointment  
Antibiotic

### **Pr SOFRAMYCIN® Eye Drops**

Framycetin sulfate eye drops  
Antibiotic

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## 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

Gramicidin is a cyclic polypeptide antibiotic. It alters the cation content of the bacterial cell wall. Gramicidin is primarily effective against gram-positive organisms.

Phenylephrine is a sympathomimetic amine which acts predominantly on alpha-adrenergic receptors. Topical application to the nasal mucosa results in the constriction of dilated arterioles and a reduction in nasal congestion. In addition, nasal secretions are reduced, and drainage of sinus secretion is increased. Nasal ventilation and aeration are improved temporarily.

## Indications and Clinical Use

*Nasal Spray* : For use in the local treatment of infections and/or congestion caused by susceptible organisms in acute rhino-sinusitis, crusting rhinitis, nasal conditions accompanying the common cold and for post-operative care of patients who have undergone intranasal or sinus surgery.

Prophylactic use, for reduction of nasal carriage of staphylococci.

*Skin Ointment*: For local use in the treatment of infections caused by pyogenic organisms, in particular *S. aureus*, the proteus group of bacteria, coliforms and *P. aeruginosa*. The treatment of bacterial infections of the skin and mucous membrane caused by susceptible bacteria. These include such conditions as pyoderma, folliculitis, paronychia, sycosis barbae, and impetigo. Also useful in controlling secondary bacterial infections in skin carcinoma, burns, eczemas, contact dermatitis, seborrhea, acne, psoriasis, varicose ulcers and neurodermatitis.

*Ophthalmic drops and ointment* : For local use in the treatment of infections caused by pyogenic organisms, in particular *S. aureus*, the proteus group of bacteria, coliforms and *P. aeruginosa*. Treatment of bacterial blepharitis, conjunctivitis, styes, corneal abrasions and burns; prophylactically following removal of foreign bodies; corneal ulcers.

## Contraindications

Known hypersensitivity to any ingredients of the preparation, especially to framycetin or other aminoglycoside antibiotics. *Soframycin Nasal Spray* contains phenylephrine; it should not be administered to patients receiving MAO inhibitors, to patients presenting narrow angle glaucoma or rhinitis sicca.(see also PRECAUTIONS) or to children under 2 years of age.

## Warnings

*Soframycin Nasal Spray*: Do not exceed recommended dosage because symptoms may occur such as burning, stinging, sneezing or increase of nasal discharge. Prolonged or excessive use may cause rebound congestion.

## Precautions

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. Prolonged use of antibiotics may result in the overgrowth of nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs.

*Soframycin Nasal Spray*: Because some individuals may be particularly sensitive to the effects of sympathomimetics, use nasal spray with caution in patients with marked hypertension, hyperthyroidism, unstable type I diabetes mellitus, severe coronary artery disease and in those receiving tricyclic antidepressants. Pregnancy and Lactation: Clinical data are inadequate to establish conditions for safe use in pregnant and lactating women. To help prevent contamination from nasal secretions, patients should rinse spray tips in hot water after each use.

## Adverse Reactions

Rarely, allergic cutaneous reaction.

*Soframycin Nasal Spray*: transient burning, stinging, dryness of the nasal mucosa and sneezing. As with other topical nasal decongestants, palpitations, tachycardia, cardiac arrhythmia, increase in blood pressure, headache, light-headedness, nervousness, insomnia, blurred vision, drowsiness and CNS depression are a possibility with high doses.

## Overdosage

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

*Soframycin Nasal Spray*: Overdosage of sympathomimetic amines such as phenylephrine in children may produce profound CNS depression, possibly requiring intensive supportive treatment.

## Dosage and Administration

*Nasal Spray*: Usual adult dosage: Two (2) sprays in each nostril every 4 hours. Maximum of 6 times per day.

For reduction of staphylococci nasal carriage: 2 sprays in each nostril twice daily.

As for any other preparation containing phenylephrine hydrochloride or related compounds, intranasal application should generally be used for no longer than 3-5 days, since it can result in rebound congestion (which may lead to rhinitis medicamentosa).

*Skin Ointment*: Apply locally 2 to 4 times a day as prescribed.

*Ophthalmic drops and ointment:* Drops (for rapid relief): from 1 - 2 drops every one or two hours in acute conditions (generally for two or three days), to 1 or 2 drops three or four times daily.

Ointment (for continued effect): 2 or 3 applications daily, or at bedtime if drops have been used during the day.

## Supplied

*Soframycin Nasal Spray:* Each mL of Nasal Spray contains 12.5 mg of framycetin (as sulfate BP), 50 µg of gramicidin USP, 2.5 mg of phenylephrine hydrochloride BP and 0.11mg of benzalkonium chloride as preservative. Other non medicinal ingredients: citric acid, isopropyl alcohol, sodium chloride, sodium citrate, Tween 80, water. Spray pumps of 15 mL.

*Soframycin Skin Ointment:* Each g of ointment contains 15mg of framycetin sulfate BP and 50µg of gramicidin USP. Other non medicinal ingredients: white soft paraffin, liquid paraffin, lanolin anhydrous and zinc stearate. Ointment is offered in tubes of 15g.

*Soframycin eye drops:* Each mL of drops (pH is 5.8 to 6.8) contains 5mg of framycetin sulfate BP and 0.12 µg of benzalkonium chloride in a sterile, buffered, isotonic aqueous solution. Other non medicinal ingredients: citric acid, sodium citrate and sodium chloride. Drops are offered in 8mL bottles.

*Soframycin sterile eye ointment:* Each g of ointment contains 5mg of framycetin sulfate BP and 995mg of plastibase 30W as a sterile, greasy ointment base. Ointment is offered in tubes of 5 g.

## Storage recommendations

Store between 15°C and 30°C.

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