

PRESCRIBING INFORMATION
INCLUDING PATIENT MEDICATION INFORMATION

PrSOFRACORT®
5 mg Framycetin sulphate, 0.05 mg Gramicidin and 0.5 mg Dexamethasone
Ophthalmic/Otic solution

Antibiotic - Corticosteroid

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PRESCRIBING INFORMATION
INCLUDING PATIENT MEDICATION INFORMATION

NAME OF DRUG

PrSOFRACORT®
5 mg Framycetin sulphate, 0.05 mg Gramicidin and 0.5 mg Dexamethasone
Ophtalmic/Otic solution

THERAPEUTIC CLASSIFICATION

Antibiotic - Corticosteroid

INDICATIONS

Eye: Blepharitis and infected eczema of the eyelid; allergic, infective and rosacea conjunctivitis; rosacea keratitis; scleritis and episcleritis; iridocyclitis, and other inflammatory conditions of the anterior segment of the eye.

Ear: Otitis externa (acute and chronic) and other inflammatory and seborrheic conditions of the external ear.

SOFRACORT contains antibacterial ingredients, framycetin and gramicidin. To reduce the development of drug-resistant bacteria and maintain the effectiveness of framycetin and gramicidin, SOFRACORT should only be used for the authorized indication.

CONTRAINDICATIONS

Eye:

- Herpes simplex and other viral diseases of the cornea and conjunctiva; tuberculosis and fungal diseases of the eye; trachoma.
- Acute purulent, untreated infections of the eye, which, like other diseases caused by micro-organisms, may be masked or enhanced by the presence of the steroid.
- Known hypersensitivity to any of the ingredients.

Ear:

- Viral and fungal infections.
- Acute purulent, untreated infections.
- Perforation of the eardrum because of the risk of ototoxicity.
- Known hypersensitivity to any of the ingredients.

WARNINGS & PRECAUTIONS

Visual disturbance may be associated with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR). Extended ophthalmic use of corticosteroids may increase intra-ocular pressure in some individuals in such cases, intra-ocular pressure should be checked regularly. In conditions causing thinning of the cornea, topical steroids may cause perforation. Cataract has occurred after prolonged treatment with topical steroids.

The safety of prolonged use of topical steroids during pregnancy has not been substantiated. The benefits of use should be weighed against possible adverse effects on the fetus.

The drug should be discontinued if there are signs of sensitivity to any of its ingredients. Patients are advised to inform the physicians of the prior use of corticosteroids.

Although it is unlikely that infants will be treated with SOFRACORT for prolonged periods, there is a risk of adrenal suppression, even without occlusive dressings, after prolonged treatment of these patients with topical steroids.

Aminoglycosides antibiotics may cause irreversible, partial or total deafness when applied topically to open wounds or damaged skin. This effect is aggravated by renal or hepatic impairment and by prolonged duration of treatment. The treatment should not be continued after resolution of symptoms.

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing SOFRACORT in the absence of the authorized indications is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

Potential for Microbial Overgrowth

The use of SOFRACORT may promote the selection of non-susceptible organisms. Should superinfection occur during therapy, appropriate measures should be taken.

ADVERSE REACTIONS (see Precautions)

Eye disorders

Increased intra-ocular pressure; perforation of the cornea; hypersensitivity; burning or stinging of the eye; blurred vision; chorioretinopathy.

DOSAGE AND ADMINISTRATION

Drops

Ear: Instill 2 or 3 drops in the ear canal 3 or 4 times daily by tilting head to one side. Squeeze the dropper carefully. To avoid possibility of reinfection later, do not touch ear with dropper. Alternatively, a saturated gauze wick may be inserted by the physician into the external auditory meatus.

Eye: In acute conditions, 1 or 2 drops every 1 to 2 hours may be instilled (generally for 2 or 3 days). Subsequently, 1 or 2 drops 3 or 4 times daily. To avoid possibility of reinfection later, do not touch eye with dropper.

STORAGE AND STABILITY

Store between 15-25° C. Do not refrigerate.

Use within four weeks of opening.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Composition:

Medicinal ingredients: dexamethasone sodium metasulfobenzoate, framycetin sulphate, gramicidin

Non-medicinal ingredients: Citric acid monohydrate, hydrochloric acid, industrial methylated spirit (IMS 66OP), lithium chloride, polysorbate 80, sodium citrate, sodium hydroxide, 2-phenyl ethanol, water for injections

In each milliliter of solution, 5 mg framycetin sulphate; 0.05 mg gramicidin; 0.5 mg dexamethasone as dexamethasone sodium metasulfobenzoate)

SOFRACORT is available in an amber glass bottle with rubber dropper bulb, containing 8 mL of solution.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr **SOFRACORT**[®]

5 mg Framycetin sulphate, 0.05 mg Gramicidin and 0.5 mg Dexamethasone
Ophthalmic/Otic solution

Read this carefully before you start taking **SOFRACORT** and each time you get a refill. 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 **SOFRACORT**.

What is **SOFRACORT** used for?

It is used in the eye(s) to treat:

- inflammation due to infection (redness, itching, swelling, burning) in the front parts of the eye:
 - white of the eye (scleritis)
 - clear layer on top of the white part of the eye (episcleritis)
 - coloured part of the eye (iritidocycitis)
 - Muscles and tissue involved in focusing the eye
- inflammation due to infection (redness, swelling, burning) of the eyelid (blepharitis)
- Infected itchy, red rash of the eyelid
- Allergic and contagious eye infections
- Face skin reddening leading to red and yellow bumps (rosacea keratitis)

It is used in the ear(s) for:

- redness and swelling of the ear canal (otitis externa)
- red, scaly, greasy, itchy and inflamed skin of the outer ear.

SOFRACORT contains antibacterial ingredients called framycetin and gramicidin, and it should be used exactly as directed by your healthcare professional.

How does **SOFRACORT** work?

SOFRACORT is a combination product that contains:

- 2 antibiotics (framycetin and gramicidin) that kill the bacteria that are causing the infection.
- 1 steroid (dexamethasone) that lowers inflammation.

What are the ingredients in **SOFRACORT**?

Medicinal ingredients: dexamethasone sodium metasulfobenzoate, framycetin sulphate, gramicidin

Non-medicinal ingredients: Citric acid monohydrate, hydrochloric acid, industrial methylated spirit (IMS 66OP), lithium chloride, polysorbate 80, sodium citrate, sodium hydroxide, 2-phenyl ethanol, water for injections

SOFRACORT comes in the following dosage forms:

Each milliliter of solution contains 5 mg framycetin sulphate; 0.05 mg gramicidin and 0.5 mg dexamethasone (as dexamethasone sodium metasulfobenzoate).

SOFRACORT is available in an amber glass bottle with rubber dropper bulb, containing 8 mL of solution.

Do not use SOFRACORT if:

Eye:

- You are allergic to any of the ingredients in SOFRACORT;
- You have herpetic eye disease or other viral diseases of the cornea and conjunctiva;
- You have tuberculosis and fungal diseases of the eye;
- You have trachoma;
- You have untreated eye infections with thick discharges.

Ear:

- You are allergic to any of the ingredients in SOFRACORT;
- You have viral or fungal infections;
- You have untreated ear infections of the ear discharges;
- Your eardrum is punctured.

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

- Used corticosteroids before.
- Have open wounds or damaged skin since deafness might happen if SOFRACORT is used directly on them.

Experience Allergies

- New itching, rash, redness or irritation that happens after using SOFRACORT.

Experience Eye Problems

- blurred vision or other changes in vision (cataracts)
- increased eye pressure
- if you take SOFRACORT for a long period of time, you should have your eye pressure checked regularly
- perforation of the cornea due to thinning of the cornea

Get Pregnant

- If you become pregnant while taking SOFRACORT, talk to your healthcare professional right away.
- SOFRACORT should not be used for a long period of time during pregnancy unless the benefits outweigh the risks.

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

How to take SOFRACORT:

Use in the Eye(s):

- Wash your hands.
 - Remove the cap on the bottle.
 - Tilt your head back. Pull down the lower lid of your eye.
 - Squeeze 1 drop at a time into the pocket made by the lower lid.
 - To avoid possibility of reinfection later, do not touch eye with dropper.
 - Close your eye.
 - Wipe away any excess drops with a clean tissue.
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- Always put the cap back on the bottle as soon as you have used it.

Use in the Ear(s):

- Wash your hands.
 - Remove the cap on the bottle.
 - Tilt your head on one side.
 - Squeeze 2 or 3 drops into your ear. Squeeze the dropper carefully.
 - Lie your head with your affected ear facing upwards for a few minutes.
 - To avoid possibility of reinfection later, do not touch ear with dropper. Alternatively, a saturated gauze wick may be inserted by the physician into the external ear canal.
 - Wipe away any excess drops with a clean tissue.
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- Always put the cap back on the bottle as soon as you have used it.

Misuse or overuse of SOFRACORT could lead to the growth of bacteria that will not be killed by framycetin or gramicidin. This means that SOFRACORT or other medicines that contain framycetin or gramicidin may not work for you in the future.

Do not share your medicine.

Usual dose:

In the eye(s)

- 1 or 2 drops every 1 to 2 hours (generally for 2 or 3 days).
- Afterwards, 1 or 2 drops 3 or 4 times daily.

In the ear(s)

- 2 or 3 drops in the ear canal 3 or 4 times daily.

Overdose:

If you think you have taken too much SOFRACORT, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

It is important to take this medication exactly as prescribed by your doctor. If you miss a dose, administer it as soon as possible and continue with your regular schedule. If it is almost time for your next dose, skip the missed dose and continue with your regular dosing schedule. Do not administer a double dose to make up for a missed one. If you are not sure what to do after missing a dose, contact your doctor or pharmacist for advice.

What are possible side effects from using SOFRACORT?

These are not all the possible side effects you may feel when taking SOFRACORT. If you experience any side effects not listed here, contact your healthcare professional.

Eye disorders

- increased eye pressure (glaucoma);
- perforation of the cornea (the transparent layer forming the front of the eye);
- eye allergies;
- burning or stinging of the eye;
- cloudy vision;
- blurred or distorted vision (chorioretinopathy).

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN Allergic reaction: <ul style="list-style-type: none">• rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever;• wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness;• swelling of the mouth, face, lips, tongue, or throat.			√
Decreased vision			√
Eye infection		√	
Eye pain			√
Gradual blurring or loss of vision			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Dizziness/feeling of spinning			√
Hearing loss			√
Ringing in the ears		√	
Unsteadiness/loss of balance			√

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.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>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.</i></p>
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Storage:

Store between 15-25° C. Do not refrigerate.

Use within 4 weeks of opening.

Keep out of reach and sight of children.

If you want more information about SOFRACORT:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer’s website www.sanofi.ca, or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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