

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

SOFRACORT

Framycetin sulphate, Dexamethasone and Gramicidin 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 (iridocyclitis)
 - 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: framycetin sulphate, dexamethasone sodium metasulfobenzoate, 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, 0.5 mg dexamethasone (as dexamethasone sodium metasulfobenzoate), and 0.05 mg gramicidin.

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

Do not use SOFRACORT if:

- You are allergic to any of the ingredients in SOFRACORT or to a component of the container;
- You have herpetic eye disease (infection caused by herpes simplex or herpes zoster virus) or other viral diseases of the cornea and conjunctiva;
- You have tuberculosis of the eye (infection caused by the bacteria *Mycobacterium tuberculosis*);
- You have trachoma (eye infection caused by the bacteria *Chlamydia trachomatis*);
- You have untreated eye or ear infections with thick discharges;
- You have glaucoma (eye condition that damages the optic nerve of the eye);
- You have viral infections of the eye or ear;
- You have fungal infections of the eye or ear;
- 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.
- Have kidney or liver impairment.
- Are diabetic. Your healthcare professional may need to increase your dose of insulin or medication.
- Have tumors of the adrenal gland called pheochromocytoma.
- Have an ototoxicity (harmful effects to the ear) or family history of ototoxicity with signs and symptoms including:
 - ringing in ears
 - imbalance (associated with dizziness, nausea, and blurry vision)
 - decreased hearing
 - hearing loss
- Know (or think) you have a mitochondrial disease (mutations in the parts of your cells which help make energy). These diseases may increase your risk of hearing loss with this product.

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.
- perforation of the cornea due to thinning of the cornea.

Get Pregnant

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

Other warnings you should know about:

Driving and Operating Machinery

SOFRACORT may cause blurred vision. Do not drive or operate dangerous machinery unless your vision is clear.

You should not take SOFRACORT for a long period of time unless your healthcare professional tells you to. If you do, your healthcare professional will check your eyes for cataracts or infections regularly. They will also check your eye pressure regularly.

You should not take SOFRACORT for red eye that has not been diagnosed by your healthcare professional. Using SOFRACORT inappropriately could cause blindness.

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.

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

The following may interact with SOFRACORT:

- Medicines called CYP3A inhibitors. These medicines use a system called CYP3A in the body. If you are not sure whether a drug you take is a CYP3A inhibitor, talk to your healthcare professional. A few examples of these medicines are:
 - clarithromycin, erythromycin (used to treat bacterial infections)
 - itraconazole, ketoconazole (used to treat fungal infections)
 - diltiazem, verapamil (used to treat chest pain)
 - ritonavir or cobicistat (used to treat HIV/AIDS)

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.
- 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.
- Always put the cap back on the bottle as soon as you have used it.

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, or a person you are caring for, have taken too much SOFRACORT, contact a 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 have when taking SOFRACORT. If you experience any side effects not listed here, tell 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			✓
Glaucoma (an eye disease that can cause loss of vision): decreased vision, loss of vision			✓
Cataracts (a condition where the lens of your eye gets cloudy): gradual blurring, loss of vision			✓
Dizziness/feeling of spinning			✓
Hearing loss			✓
Ringing in the ears		✓	
Unsteadiness/loss of balance			✓
Iatrogenic Cushing's Syndrome (a disorder caused by high levels of cortisol): abnormal obesity with thin arms and legs, acne, high blood pressure, rounded face			✓
Adrenal atrophy (a condition where the adrenal gland does not produce enough cortisol): dehydration, disorientation, low blood sugar, weight loss			✓
Diabetes mellitus (a condition where blood sugar is high): frequent urination, increased thirst and hunger, weight loss			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) 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 between 15 to 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://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); 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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