PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

Pr**SOFRACORT®**

Framycetin sulphate, Dexamethasone and Gramicidin Ophthalmic/Otic Solution

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

Antibiotic - Corticosteroid

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RECENT MAJOR LABEL CHANGES

2 Contraindications	11/2020
7 Warnings and Precautions, Driving and Operating Machinery	11/2020
7 Warnings and Precautions, Ear/Nose/Throat	11/2022
7 Warnings and Precautions, Endocrine and Metabolism	11/2020
7 Warnings and Precautions, Neurologic	11/2020
7 Warnings and Precautions, Ophthalmologic	11/2020
7 Warnings and Precautions, Sensitivity/Resistance	11/2020

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Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

SOFRACORT (framycetin sulphate, dexamethasone and gramicidin ophthalmic/otic solution) is indicated for:

- **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.

1.1 Pediatrics

Pediatrics (< 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use (see 7.1.3 Pediatrics).

1.2 Geriatrics

Geriatrics: No data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use.

2 CONTRAINDICATIONS

SOFRACORT is contraindicated in patients with:

- Known hypersensitivity to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.

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.
- Glaucoma.

Ear:
- Viral and fungal infections.
- Acute purulent, untreated infections.
- Perforation of the eardrum because of the risk of ototoxicity.

4 DOSAGE AND ADMINISTRATION

4.2 Recommended Dose and Dosage Adjustment

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.

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.

Pediatrics (< 18 years of age):
Health Canada has not authorized an indication for pediatric use (see 1.1 Pediatrics).

4.5 Missed Dose

If a dose is missed, it should be administered as soon as possible, and the regular dosage schedule should be resumed. If it is almost time for the next dose, the missed dose should be skipped, and the regular dosing schedule should be resumed. A double dose should not be administered.

5 OVERDOSAGE

Long-term intensive topical use may lead to systemic effects.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form/ Strength/Composition	Non-medicinal Ingredients
Ophthalmic/Otic	Solution 5 mg/mL Framycetin sulphate 0.5 mg/mL Dexamethasone 0.05 mg/mL Gramicidin	Citric acid monohydrate, hydrochloric acid, industrial methylated spirit (IMS 66OP), lithium chloride, polysorbate 80, sodium citrate, sodium hydroxide, 2-phenyl ethanol, water for injection

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.

7 WARNINGS AND PRECAUTIONS

Driving and Operating Machinery

SOFRACORT may cause transient blurring of vision on instillation. If blurred vision occurs after SOFRACORT administration, the patient must wait until vision clears before driving or operating machinery.

Ear/Nose/Throat

Aminoglycoside 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.

There have been reported cases of an increased risk of ototoxicity with aminoglycosides administered to patients with mitochondrial mutations, particularly the nucleotide 1555 A to G substitution in the 12S rRNA gene, including cases where the patient's aminoglycoside serum levels were within the recommended range. Some cases were associated with a maternal history of deafness and/or mitochondrial mutation. Mitochondrial mutations are rare, and the penetrance of this observed effect is unknown.

Based on a shared mechanism of action with other aminoglycosides, the risk of ototoxicity with framycetin and other topical aminoglycosides cannot be ruled out.

Endocrine and Metabolism

During therapy with SOFRACORT, a possibly increased need for insulin or antidiabetics should be considered in patients with diabetes (see 8.5 Post-Market Adverse Reactions).

Immune

Discontinue SOFRACORT if there are signs of sensitivity to any of its ingredients. Patients are advised to inform the physicians of the prior use of corticosteroids (see 2 CONTRAINDICATIONS and 8.5 Post-Market Adverse Reactions).

In patients known to be allergic to other aminoglycoside antibiotics (neomycin, kanamycin), cross-sensitization to framycetin may occur, but not invariably so.

Neurologic

Pheochromocytoma crisis, which can be fatal, has been reported after administration of corticosteroids. Corticosteroids should only be administered to patients with suspected or identified pheochromocytoma after an appropriate risk/benefit evaluation.

Ophthalmologic

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). Treatment with corticosteroid

preparations should not be repeated or prolonged without regular review to exclude raised intraocular pressure, cataract formation or unsuspected infections. In conditions causing thinning of the cornea, topical steroids may cause perforation. Cataract has occurred after prolonged treatment with topical steroids (see 8.5 Post-Market Adverse Reactions).

Topical corticosteroids should never be given for an undiagnosed red eye as inappropriate use is potentially blinding.

Sensitivity/Resistance

Treatment with corticosteroid/antibiotic combinations should not be continued in the absence of clinical improvement, since prolonged use may lead to occult extension of infections due to the masking effect of the steroid. Prolonged use may also lead to skin sensitization and the emergence of resistant organisms.

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.

7.1 Special Populations

7.1.1 Pregnant Women

There are no available data on SOFRACORT use in pregnant women. The safety of prolonged use of topical steroids during pregnancy has not been substantiated. No conclusions can be drawn regarding whether or not SOFRACORT is safe for use during pregnancy. SOFRACORT should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the fetus.

7.1.2 Breast-feeding

There are no available data on the presence of SOFRACORT in human milk, milk production, or the effects on the breast-fed infant. No conclusions can be drawn regarding whether or not SOFRACORT is safe for use during breast-feeding. SOFRACORT should be used during breast-feeding only if the potential benefits to the mother outweigh the potential risks, including those to the breast-fed child.

7.1.3 Pediatrics

Pediatrics (< 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use (see 1.1 Pediatrics).

There is a risk of adrenal suppression, even without occlusive dressings, after prolonged treatment of infants with topical steroids.

8 ADVERSE REACTIONS

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. The adverse reaction rates observed in the clinical trials; therefore, may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials may be useful in identifying and approximating rates of adverse drug reactions in real-world use.

Eye disorders
Increased intra-ocular pressure; perforation of the cornea; hypersensitivity; burning or stinging of the eye.

8.5 Post-Market Adverse Reactions

Endocrine disorders
Iatrogenic Cushing's syndrome; adrenal atrophy.

Eye disorders
Blurred vision; chorioretinopathy; increased intra-ocular pressure leading to optic nerve damage, reduced visual acuity and visual field defects; glaucoma; cataracts.

Immune disorders
Hypersensitivity reactions, usually of the delayed type, may occur, leading to irritation, burning, stinging, itching and dermatitis.

Metabolism and nutrition disorders
Diabetes mellitus; decreased glucose tolerance.

9 DRUG INTERACTIONS

9.4 Drug-Drug Interactions

The drugs listed in this table are based on either drug interaction case reports or studies, or potential interactions due to the expected magnitude and seriousness of the interaction (i.e., those identified as contraindicated).

Table 2 - Established or Potential Drug-Drug Interactions

Proper/ Common name	Source of Evidence	Effect	Clinical comment
CYP3A inhibitors	T	Increased risk of side effects	Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of such side-effects, in which case patients should be monitored.

Legend: T = Theoretical

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

This information is not available for this drug product.

11 STORAGE, STABILITY AND DISPOSAL

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

Use within four weeks of opening.

12 SPECIAL HANDLING INSTRUCTIONS

This information is not available for this drug product.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

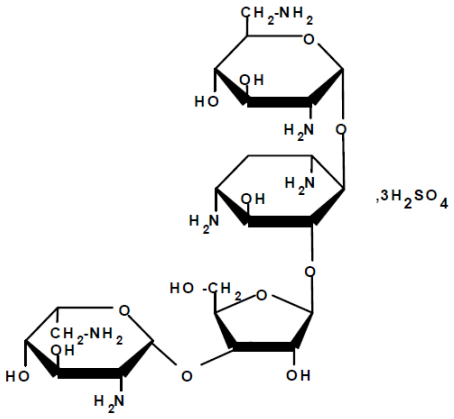
Proper name: Framycetin sulphate or Neomycin B sulphate

Chemical name: Sulphate of 2-deoxy-4-O-(2,6-diamino-2,6-dideoxy-α-D-glucopyranosyl)-5-O-[3-O-(2,6-diamino- 2,6-dideoxy-β-L-idopyranosyl)-β-D-ribofuranosyl]-D-streptamine

Molecular formula: $C_{23}H_{46}N_6O_{13}, 3H_2SO_4$

Molecular mass: Mr 908.9 (Framycetin sulphate); Mr 614.6 (Framycetin)

Structural formula:



Physicochemical properties: Hygroscopic, white to slightly yellowish powder, not granular to the touch. Framycetin sulphate is highly soluble in water, very slightly soluble in alcohol and practically insoluble in acetone, chloroform and ether. Not more than 80 mcg can be dissolved in 1 mL of cyclohexane.

Drug Substance

Proper name: Dexamethasone sodium metasulfobenzoate or Dexamethasone 21 (sodium metasulfobenzoate)

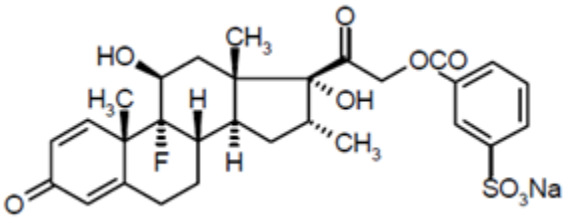
Chemical name: (11β,16α 9-Fluoro-11, 17-dihydroxy-16-methyl-21-[(3-sulfobenzoyl)oxy]-pregna-1, 4-diene-3, 20-dione Monosodium salt

(9α-Fluoro-11 β, 17 α -dihydroxy-16 α -methyl-3, 20-dioxopregna-1, 4-dien-21-yl), m-sulfobenzoate, sodium salt

Molecular formula: $C_{29}H_{32}FNaO_9S$

Molecular mass: Mr = 598.6 (Dexamethasone sodium metasulfobenzoate);
Mr = 392.5 (Dexamethasone)

Structural formula:



Physicochemical properties: White to practically white microcrystalline powder. The polymorphism analyses show the crystalline form I. In addition to an amorphous form, 10 crystalline forms (solvate, hydrate and anhydrous forms) were identified during the polymorph screening. The water content, the TGA and DSC results show that form I is a monohydrate form.

Solvent	Descriptive term	Solubility (g/L)
Water	Soluble	between 30 and 100
Acetone	Sparingly soluble	between 10 and 30
Ether	Sparingly soluble	between 10 and 30

Drug Substance

Proper name: Gramicidin

Chemical name: Gramicidin A1 (Val-Gram A)
Gramicidin A2 (Ile-Gram A)
Gramicidin B1 (Val-Gram B)
Gramicidin C1 (Val-Gram C)
Gramicidin C2 (Ile-Gram C)

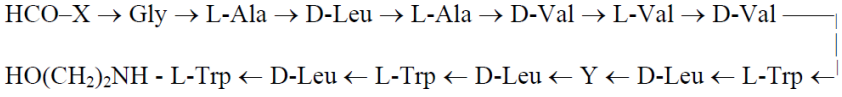
Molecular formula: Gramicidin A1: $C_{99}H_{140}N_{20}O_{17}$
Gramicidin A2: $C_{100}H_{142}N_{20}O_{17}$
Gramicidin B1: $C_{97}H_{139}N_{19}O_{17}$
Gramicidin C1: $C_{97}H_{139}N_{19}O_{18}$
Gramicidin C2: $C_{98}H_{141}N_{19}O_{18}$

Molecular mass: Gramicidin A1: 1882 g/mol
Gramicidin A2: 1896 g/mol
Gramicidin B1: 1843 g/mol
Gramicidin C1: 1859 g/mol
Gramicidin C2: 1873 g/mol

Structural formula:

The gramicidins constitute a family of end-substituted linear pentadecapeptides where the N-terminal amino group is formylated and the C-terminal carboxylic group is amidated with ethanolamine. Change of the two amino acids elements (first and eleventh) of the polypeptide chain gives the components of the gramicidin family: A1, A2, B1, C1 and C2.

The general structure of the gramicidins is:



The peptide bond is indicated by →.

The amino acid at X and that at Y for each component of the gramicidin family is indicated in the table below:

Gramicidin A1	X = L-Val	Y = L-Trp
Gramicidin A2	X = L-Ile	Y = L-Trp
Gramicidin B1	X = L-Val	Y = L-Phe
Gramicidin C1	X = L-Val	Y = L-Tyr
Gramicidin C2	X = L-Ile	Y = L-Tyr

Physicochemical properties: Gramicidin is a white or almost white, crystalline powder. It is slightly hygroscopic. It is very stable both in the dry form and in solution, also at elevated temperatures. Gramicidin is practically insoluble in water, sparingly soluble in alcohol, and soluble in methanol.

14 CLINICAL TRIALS

This information is not available for this drug product.

15 MICROBIOLOGY

This information is not available for this drug product.

16 NON-CLINICAL TOXICOLOGY

This information is not available for this drug product.

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: • 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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