

Sofradex[®]

Framycetin sulfate (fra-me-see-tin sul-fate), Gramicidin (grammy-sigh-din), Dexamethasone (dex-ar-meth-ar-sona)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Sofradex.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using Sofradex against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Sofradex is used for

Sofradex is a medicine used to treat infection or inflammation of the ear or eye. Sofradex contains antibiotics (framycetin sulfate and gramicidin) to kill germs and a corticosteroid (dexamethasone) to stop inflammation, itching and weeping.

This medicine is available only with a doctor's prescription.

Before you use it

When you must not use it

Do not use Sofradex if you have an allergy to Sofradex or any of the ingredients listed at the end of this leaflet.

Do not use Sofradex if you are allergic to framycetin, gramicidin or dexamethasone.

Do not use Sofradex if you have:

- a hole in your eardrum
- viral, fungal or tubercular (nodular) lesions
- chicken pox (varicella virus)
- vaccinia – a type of virus
- pus-containing conditions of the eye or ear
- high pressure in the eye (glaucoma)
- herpes of the eye (eg dendritic ulcer)
- undiagnosed red eye or eyelid swelling

Do not use Sofradex if you are pregnant or intend to become pregnant.

Like most aminoglycosides, Sofradex is not recommended for use during pregnancy.

Do not use Sofradex after the expiry date (EXP) printed on the pack.

If you use this medicine after the expiry date has passed, it may not work as well.

Do not use Sofradex if the packaging is torn or shows signs of tampering, or if it doesn't look quite right.

If you are not sure whether you should start using Sofradex, contact your doctor or pharmacist.

Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

- framycetin, gramicidin or dexamethasone
- any other medicines, especially antibiotics such as neomycin, and kanamycin

- any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Sofradex is not recommended to be used during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of using it if you are pregnant.

Tell your doctor if you are breastfeeding or intend to breastfeed.

The effects on breastfeeding have not been studied.

Tell your doctor if you are diabetic.

The dose of your medication may need to be adjusted.

Tell your doctor if you:

- Have an ototoxicity or family history of ototoxicity (harmful effects to ear) with signs and symptoms including ringing in ears, imbalance (associated with dizziness, nausea, and blurry vision), decreased hearing, hearing loss.
- now (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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are taking any HIV medications, medicines to treat irregular heartbeats or other antibiotics or antifungals.

How to use it

Use Sofradex only as directed by your doctor. Generally this will be as follows:

Ear Drops: The drops are usually used 3 or 4 times daily.

Sofradex Drops for the ear may be used following the steps below:

1. Wash your hands well with soap and water.
2. Shake the bottle.
3. Remove the cap from the bottle immediately before use and place it back on the bottle immediately after use.
4. Tilt your head so that the affected ear is uppermost.
5. Position the rubber dropper, which is attached to the bottle, directly above the ear hole.
6. With the bottle tipped upside down, gently squeeze the rubber dropper until 2 or 3 drops fall into the ear.
7. Keep your head tilted for about a minute to allow the drops to penetrate deep into the ear.
8. Wash your hands again with soap and water to remove any residue.

Eye Drops: The drops are usually used up to six times daily or more frequently if required.

Sofradex Drops for the eye may be used following the steps below:

You may find it easier to put drops in your eye while you are sitting or lying down.

1. Wash your hands well with soap and water.
2. Shake the bottle.
3. Remove the lid.
4. Hold the bottle upside down in one hand between your thumb and middle finger.
5. Using your other hand, gently pull down your lower eyelid to form a pouch.
6. Tilt your head back and look up.
7. Put the tip of the bottle close to your eye. Do not let it touch your eye.
8. Release one drop onto your eye by gently squeezing/tapping or

pressing the base of the bottle with your index finger.

9. Close your eye. Do not blink or rub your eye.
10. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about 2 minutes. This will help stop the medicine draining through the tear duct to the nose or throat, from where it can be absorbed into other parts of your body. Ask your doctor or pharmacist for more specific instructions on this technique.
11. Repeat steps 4-10 to instil the second drop if required or follow the directions given to you by your doctor and pharmacist.
12. Replace the lid, sealing it tightly.
13. Wash your hands again with soap and water to remove any residue.

Your doctor may decide to adjust your dosage if necessary or ask you to use Sofradex in a different way, according to his or her judgment.

Ask your pharmacist for advice if you need further instructions on how best to use Sofradex.

How long to use it

Continue using Sofradex until your doctor or pharmacist tells you to stop.

Do not stop using it unless your doctor or pharmacist tells you to even if you feel better.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

While you are using it

Things you must do

Use Sofradex only in the ear or eye unless your doctor advises differently. Contact your doctor promptly if:

- your condition worsens during treatment
- an allergic reaction develops
- you feel no better after completing the prescribed treatment

If you become pregnant while using Sofradex, stop using it and tell your doctor or pharmacist immediately.

Things you must not do

Do not give Sofradex to anyone else, even if they have the same condition as you.

Do not use Sofradex to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop using Sofradex, or lower the dosage, without checking with your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Sofradex affects you.

Sofradex causes blurring of vision on application. Make sure your vision is clear before you drive a car, operate machinery, or do anything else that could be dangerous if your vision is blurred.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Sofradex, even if the problem is not listed below.

Sofradex helps most people with an infection or inflammation of the ear or eye, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- local allergic reaction: redness, pain, itching, stinging, weeping or swelling around the site of application.
- blurred vision or reduced sharpness of vision
- loss of vision
- eye irritation or having a feeling of something in the eye.
- weight gain
- rounded (moon-shaped) face
- high blood pressure
- weakness
- tiredness
- weight loss
- dizziness or light-headedness
- high blood sugar which may present as excessive thirst, increased appetite, feeling tired or passing large amounts of urine.

These are the more common side effects of Sofradex. Mostly these are mild and short-lived.

Other side effects not listed above may occur in some patients.

After using it

Storage

Keep Sofradex in a cool dry place where the temperature stays below 25°C. Do not refrigerate.

Do not store Sofradex or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop using Sofradex or if it has passed the expiry date, ask your pharmacist what to do with any that is left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Sofradex ear/eye drops is supplied as a sterile clear solution in a glass dropper bottle.

Ingredients

Active ingredients:

- framycetin sulfate (5 mg/mL)
- gramicidin (0.05 mg/mL)
- dexamethasone (0.5 mg/mL)

Inactive ingredients:

- phenethyl alcohol (preservative)
- polysorbate 80
- methylated spirit - industrial
- citric acid monohydrate
- sodium citrate dihydrate
- lithium chloride
- sodium hydroxide (for pH-adjustment)
- hydrochloric acid (for pH-adjustment)
- water - purified

Supplier

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PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

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