

Sofradex® Ear Drops

Framycetin sulfate, Gramicidin, Dexamethasone

Consumer Medicine Information

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. 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 or tubercular lesions
- chicken pox (varicella virus)
- vaccinia - a type of virus

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, paromomycin 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.

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.

How to use it

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

The drops are usually used 3 or 4 times daily. Remove the cap from the bottle immediately before use and place it back on the bottle immediately after use. To use the drops, tilt your head so that the affected ear is uppermost. Position the rubber dropper, which is attached to the bottle, directly above the ear hole. With the bottle tipped upside down, gently squeeze the rubber dropper until 2 or 3 drops fall into the ear. Keep your head tilted for about a minute to allow the drops to penetrate deep into the ear.

Do not apply to open wounds or damaged skin.

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 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.

Do not apply Sofradex to open wounds or damaged skin, as this may cause irreversible, partial or total deafness. These effects may be aggravated by kidney or liver problems, or prolonged use. Do not continue treatment after these symptoms have resolved.

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, 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: pain, itching, stinging, weeping or swelling around the site of application.

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 the medicine has passed its 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 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
- industrial methylated spirit
- citric acid monohydrate
- sodium citrate dihydrate
- lithium chloride
- sodium hydroxide
- hydrochloric acid
- purified water

Supplier

Sofradex is supplied in Australia by:

sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113
Freecall No: 1800 818 806

This leaflet was prepared April 2020

Australian Registration Number

Sofradex Ear Drops: AUST R
13539
sofradex-ccds3-cmiv7-29apr20