

Sofradex® Ear Drops

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Sofradex?

Sofradex contains the active ingredients framycetin sulfate, gramicidin and dexamethasone. Sofradex is 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.

For more information, see Section [1. Why am I using Sofradex?](#) in the full CMI.

2. What should I know before I use Sofradex?

Do not use if you have ever had an allergic reaction to Sofradex or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Sofradex?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Sofradex and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Sofradex?

- Generally Sofradex drops are used 3 or 4 times daily
- To use, tilt your head so that the affected ear is uppermost. Position the rubber dropper 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.

More instructions can be found in Section [4. How do I use Sofradex?](#) in the full CMI.

5. What should I know while using Sofradex?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Sofradex.• Use Sofradex only in the ear unless your doctor advises differently.• If you become pregnant while using Sofradex, stop using it and tell your doctor or pharmacist immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine, or lower the dosage, without checking with your doctor or pharmacist• Do not use Sofradex to treat any other complaints unless your doctor or pharmacist tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Sofradex affects you.
Looking after your medicine	<ul style="list-style-type: none">• 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.

For more information, see Section [5. What should I know while using Sofradex?](#) in the full CMI.

6. Are there any side effects?

Side effects include local allergic reaction: pain, itching, stinging, weeping or swelling around the site of application.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Sofradex®

Active ingredients: Framycetin sulfate, Gramicidin, Dexamethasone

Consumer Medicine Information (CMI)

This leaflet provides important information about using Sofradex. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Sofradex.**

Where to find information in this leaflet:

- [1. Why am I using Sofradex?](#)
- [2. What should I know before I use Sofradex?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Sofradex?](#)
- [5. What should I know while using Sofradex?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Sofradex?

Sofradex contains the active ingredients framycetin sulfate, gramicidin and dexamethasone. Sofradex contains antibiotics (framycetin sulfate and gramicidin) to kill germs and a corticosteroid (dexamethasone) to stop inflammation, itching and weeping

Sofradex is used to treat infection or inflammation of the ear.

2. What should I know before I use Sofradex?

Warnings

Do not use Sofradex if:

- you are allergic to framycetin sulfate, gramicidin, dexamethasone, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you are pregnant or intend to become pregnant
- you have a hole in your eardrum
- you have viral or tubercular lesions
- you have chicken pox (varicella virus)
- you have vaccinia - a type of virus

Do not use Sofradex after the expiry date 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.

Tell your doctor if you:

- have allergies to framycetin, gramicidin or dexamethasone
- have allergies to any other medicines, especially antibiotics such as neomycin, paromomycin and kanamycin
- have allergies to any other substance, such as foods, preservatives or dyes

- 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
- 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.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

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

Like most aminoglycosides, Sofradex is not recommended for use during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of using it if you are pregnant.

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

3. What if I am taking other medicines?

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Sofradex.

4. How do I use Sofradex?

How much to use

- Follow the instructions provided by your doctor when Sofradex was prescribed, including the number of days it should be used.
- Generally, the drops are used 3 or 4 times daily

How to use Sofradex

- 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.

How long to use Sofradex

- 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 Sofradex

Sofradex should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take 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.

Do not take a double dose to make up for the dose you missed.

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.

If you use too much Sofradex

If you think that you have used too much Sofradex, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Sofradex?

Things you should do

Use Sofradex only in the ear unless your doctor advises differently.

Call your doctor straight away if:

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

Remind any doctor, dentist or pharmacist you visit that you are using Sofradex.

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

Things you should not do

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Sofradex affects you.

Sofradex may cause dizziness in some people

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> local allergic reaction: pain, itching, stinging, weeping or swelling around the site of application 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Sofradex contains

Active ingredient (main ingredient)	framycetin sulfate (5 mg/mL) gramicidin (0.05 mg/mL) dexamethasone 0.5 mg/mL
Other ingredients (inactive ingredients)	phenethyl alcohol (preservative) polysorbate 80 industrial methylated spirit citric acid monohydrate sodium citrate dihydrate lithium chloride sodium hydroxide hydrochloric acid purified water

Do not take this medicine if you are allergic to any of these ingredients.

What Sofradex looks like

Sofradex Ear Drops is supplied as a sterile clear solution in a glass dropper bottle (Aust R 13539).

Who distributes Sofradex

Sofradex is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall No: 1800 818 806

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