

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Sofradex® ear/eye drops, solution

(framycetin sulphate, dexamethasone sodium metasulphobenzoate, gramicidin)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Sofradex ear/eye drops, solution but will be referred to as Sofradex drops throughout this leaflet.

What is in this leaflet

1. What Sofradex drops are and what they are used for
2. What you need to know before you use Sofradex drops
3. How to use Sofradex drops
4. Possible side effects
5. How to store Sofradex drops
6. Contents of the pack and other information

1. What Sofradex drops are and what they are used for



Sofradex drops contains three medicines called Framycetin sulphate, Gramicidin and Dexamethasone sodium metasulphobenzoate.

- Framycetin sulphate and Gramicidin belong to a group of medicines called antibiotics. These work by killing the bacteria that is causing the infection.
- Dexamethasone sodium metasulphobenzoate. This belongs to a group of medicines called steroids. It works by lowering inflammation

What Sofradex drops are used for

It is used in the eye(s) for:

- Inflammation in the eye when prevention of bacterial infection is also needed. Signs include sore, red or swollen eyes.

It is used in the ear(s) for:

- Inflammation of the ear canal (otitis externa)

2. What you need to know before you use Sofradex drops



Do not use Sofradex drops:

- If you are allergic (hypersensitive) to framycetin sulphate, dexamethasone sodium metasulphobenzoate, gramicidin or any of the other ingredients of this medicine (listed in section 6).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat, tongue and worsening of redness, itching or swelling of the eye or eyelid
- Your eye or ear inflammation is due to an infection caused by a fungus or a virus.



- You have untreated eye or ear infections caused by microorganisms that may be masked or enhanced by the steroids.

if you are using these drops in your eye and:

- your eye inflammation is due to an infection called tuberculosis (TB).
- you have pus in your eye(s).
- you have eye pain or eyelid swelling or a red eye, the cause of which has not been diagnosed. Inappropriate use is potentially blinding.
- you have glaucoma.
- you have an ulcer in your eye(s) caused by the herpes simplex virus (herpetic keratitis).

if you are using these drops in your ear and:

- you have pus in your ear(s).
- you have a damaged (perforated) eardrum.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Sofradex drops.

Warnings and precautions

Talk to your doctor or pharmacist before using Sofradex drops if:

- You experience blurred vision or other visual disturbances.
- You have 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.
- You 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.

Prolonged use may lead to allergy and the emergence of non-susceptible (resistant) bacteria. Repeated and prolonged use (more than 7 days) requires monitoring of intraocular pressure due to the risk of glaucoma, cataract formation or unsuspected infections. Prolonged use in children and infants may lead to the risk of partial or total deafness.

Other medicines and Sofradex drops

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

- Some medicines may increase the effects of Sofradex drops and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before using this medicine if:

- You are pregnant, might become pregnant, or think you may be pregnant.
- You are breast-feeding or planning to breast-feed.



Driving and using machines

You may have blurred eyesight straight after using Sofradex drops. If this happens, do not drive or use any tools or machines until you can see clearly.

3. How to use Sofradex drops

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How to use this medicine

- This medicine can be used in the eye and the ear
- Do not use this medicine for more than 7 days without talking to your doctor

Use in the eye

- Wash your hands
- Remove the cap on the bottle
- Tilt your head back
- Squeeze one or two drops inside the lower lid without touching your eye with the bottle
- 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

- Wash your hands
- Remove the cap on the bottle
- Tilt your head on one side
- Squeeze two or three drops into your ear
- Lie your head with your affected ear facing upwards for a few minutes
- Wipe away any excess drops with a clean tissue
- Always put the cap back on the bottle as soon as you have used it

How much to use

In the eye(s)

- One or two drops in the affected eye six times a day or more if advised by your doctor
- Keep using Sofradex drops as instructed by your doctor

In the ear(s)

- Two or three drops in the ear three or four times a day
- Keep using Sofradex drops as instructed by your doctor

If you forget to use Sofradex drops

If you forget a dose, put some in as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. **Do not** use a double dose to make up for a forgotten dose.

If you stop using Sofradex drops

Keep using these drops until your doctor tells you to stop. Otherwise, you could get an infection, or the inflammation could get worse.



If you have any further questions on the use of medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them

Stop using Sofradex drops and see a doctor as soon as possible if:

- You get any kind of skin problem, such as a rash or itching around your eyes or irritation, increased sweating, burning, stinging, itching or swelling or eczema of the eye or ear area.
- Your eyes have problems focussing or develop a blind spot. You may have increased pressure in the eye (glaucoma).
- You have difficulty seeing at night or notice that your eyesight is cloudy and fuzzy, or you see halos around lights. These could be signs of cataracts. This may occur after using the medicine for a long time.
- You experience blurred vision.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Sofradex drops

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not refrigerate.
- Sofradex drops are sterile when you buy them.
- Discard contents 28 days after first opening.
- Do not use the drops after the expiry date which is stated on the carton and bottle labels after 'Exp'. The expiry date refers to the last day of that month.
- If the drops become discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
- Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Sofradex drops contains

The active ingredients in the Sofradex drops are framycetin sulphate, dexamethasone sodium metasulphobenzoate and gramicidin.

Each bottle contains 0.5% w/v of framycetin sulphate, dexamethasone sodium meta-sulphobenzoate (equivalent to 0.050% w/v of dexamethasone) and 0.005% w/v of gramicidin.

The other ingredients are citric acid, sodium citrate, lithium chloride, phenylethyl alcohol, industrial methylated spirit, polysorbate 80, water for injection. sodium hydroxide and hydrochloric acid (pH adjustment).

What Sofradex looks like and contents of the pack

Sofradex drops is sterile, clear and colourless ear/eye drops. Sofradex drops is available in 8ml and 10ml dropper bottle.

Manufactured by:

Patheon UK Limited, Covingham, Swindon, Wiltshire, SN3 5BZ, UK. **(For pack size 10ml) OR**
Zentiva k.s., U Kabelovny 130, 102 37 Prague, Czech Republic. **(For pack size 8ml)**

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Sofradex® ear/eye drops, solution; PL 18799/2844

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