



PACKAGE LEAFLET:
INFORMATION FOR THE USER

Sofradex Ear/Eye Drops

Framycetin sulphate 5mg/ml
Gramicidin 0.05mg/ml
Dexamethasone sodium
metasulphobenzoate 0.5mg/ml

SANOFI 



Is this leaflet hard
to see or read?
Phone 01 403 5600 for help

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Sofradex Drops are and what they are used for
2. Before you use Sofradex Drops
3. How to use Sofradex Drops
4. Possible side effects

5. How to store Sofradex Drops
6. Further information

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



What Sofradex Drops are

Sofradex Ear/Eye Drops (called Sofradex Drops in this leaflet) 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. Before you use Sofradex Drops



Do not use this medicine and tell your doctor if:

You are allergic (hypersensitive) to framycetin sulphate, dexamethasone sodium metasulphobenzoate, gramicidin or any of the other ingredients of Sofradex Drops (listed in Section 6 below)
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

If you are using these drops in your eye

Your eye inflammation is due to an infection caused by a fungus or a virus
Your eye inflammation is due to an infection called tuberculosis (TB)
You have red eye, the cause of which has not been diagnosed
You wear contact lenses
You have pus in your eye(s)
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

You have a damaged (perforated) ear drum

If any of the above apply to you or if you are unsure please talk to your doctor or pharmacist before using Sofradex.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Sofradex
Do not use Sofradex for longer than 7 days without talking to your doctor
Talk to your doctor if you experience swelling and weight gain around the trunk and in the face as these are usually the first manifestations of a syndrome called Cushing's syndrome. Suppression of the adrenal gland function may develop after stopping a long-term or intensive treatment with Sofradex. Sofradex, should not be applied to open wounds or damaged skin as it may potentially cause deafness. If this happens, contact your doctor immediately. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a drug called ritonavir or cobicistat. Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and Sofradex

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Some medicines may increase the effects of Sofradex and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat). Tell your doctor if you are using ritonavir

or cobicistat, as this may increase the amount of dexamethasone in the blood.

Pregnancy and breast-feeding

Talk to your doctor before using this medicine if you are pregnant, might become pregnant, or think you may be pregnant.
If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking or using any medicine.



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 Sofradex Drops exactly as your doctor has told you. You should 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 use more Sofradex Drops than you should

If you use too much of your medicine you



should tell your doctor or pharmacist as soon as possible.

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 this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Sofradex Drops can cause side effects, although not everybody gets them

Stop using Sofradex Drops and see a doctor as soon as possible if;

- You have an allergic reaction such as irritation, rash, burning, stinging, itching, swelling or eczema of the eye or ear area.

If using in your Eye(s)

- Your eyes have problems focussing or develop a blind spot. You may have

increased pressure in the eye

- 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. Long term use may also lead to the risk of adrenal suppression in infants.
- Blurred vision

If using in your Ear(s)

- You find that your hearing is affected. This is more likely to happen if you have any damaged skin.

Side Effects (Frequency unknown)

Hormone problems: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the levels of protein and calcium in your body, stunted growth in children and teenagers and swelling and weight gain of the body and face (called 'Cushing's syndrome') (see section 2, "Warnings and precautions").
Blurred vision
Chorioretinopathy, a disease of the eye

Talk to your doctor or pharmacist if you get any of the side effects or if you notice any side effects not listed in this leaflet.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: + 35316764971; Fax: + 3531 6762517.
Website: www.hpra.ie; email: medsafety@hpra.ie.

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

5. How to store Sofradex Drops

Keep this medicine in a safe place where children cannot see or reach it.
Do not use Sofradex Drops after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.
Do not store above 25°C. Do not refrigerate.
Sofradex Drops are sterile when you buy them, so you must not keep them for more than four weeks after opening the bottle. 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. Further information

What Sofradex Drops contains

- The Sofradex Ear/Eye Drops Solution contain the active substances: framycetin sulphate 0.5%w/v (5mg/ml), dexamethasone (as sodium metasulphobenzoate) 0.05% w/v (0.5mg/ml) and gramicidin 0.005% w/v (0.05mg/ml).
- The other ingredients are anhydrous citric acid, sodium citrate, lithium chloride, phenylethyl alcohol, industrial methylated spirit, polysorbate 80, water for injection, sodium hydroxide (for pH adjustment) and hydrochloric acid (for pH adjustment).

What Sofradex Drops looks like and contents of the pack

Sofradex® Drops are clear colourless ear/eye drops. The drops are also available in 5ml, 8ml and 10ml dropper bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Sanofi-Aventis Ireland Ltd., T/A SANOFI
Citywest Business Campus
Dublin 24.
Tel: + 353 1 403 5600
Fax: + 353 1 403 5687
email: IEMedinfo@sanofi.com

Manufacturer

Zentiva k.s., U Kabelovny 130, 102 37
Prague, Czech Republic

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

**This leaflet was last revised
in May 2019**