

# Sofradex®

## Ear/Eye Drops

framycetin sulphate 0.5%  
dexamethasone (as dexamethasone sodium metasulphobenzoate) 0.05%  
gramicidin 0.005%

sanofi aventis

### 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 framycetinsulphate, 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 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.

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.

#### 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 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 get any kind of skin problem, such as a rash or itching around your eyes or irritation burning, stinging, itching or swelling.

- 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.

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.

### 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 label and carton. The expiry date refers to the last day of that month.

Store below 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 eye drops contain the active substances; framycetin sulphate (0.5%w/v), dexamethasone sodium metasulphobenzoate (equivalent to 0.050% w/v of dexamethasone) and gramicidin (0.005%w/v).

- The other ingredients are citric acid, sodium citrate, lithium chloride, phenylethyl alcohol, industrial methylated spirit, polysorbate 80 and purified water.

#### 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, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

#### Manufacturer

Patheon UK Limited, Covingham, Swindon, Wiltshire, SN3 5BZ

This leaflet was last revised in 10/2007

SDE 86171