Soframycin®

Framycetin Sulfate (fra-me-see-tin sul-fate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Soframycin.

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 has weighed the risks of you using Soframycin against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Soframycin is used for

Soframycin is used to treat bacterial infection of the eye or ear. Soframycin is an antibiotic of the aminoglycoside class. It works by killing bacteria.

Your doctor may have prescribed Soframycin for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Your doctor may have prescribed it for another reason.

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

Before you use it

When you must not use it

Do not use Soframycin if you have an allergy to Soframycin or any of the ingredients listed at the end of this leaflet.

Do not use Soframycin in your ear if you have a hole in your eardrum (tympanic membrane).

Do not use Soframycin if you are pregnant or intend to become pregnant.
Like most aminoglycosides, Soframycin is not recommended for use during pregnancy

Do not use Soframycin 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 Soframycin 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 Soframycin, contact your doctor or pharmacist.

Before you start to use it

Tell your doctor if you have allergies to:

- antibiotics, especially framycetin
- 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, Soframycin 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.

Soframycin may affect your developing baby if you use it during pregnancy.

Tell your Doctor or Pharmacist if you are breast feeding or intend to breast feed your baby.
It is not known whether Soframycin may affect your developing baby if you use while breast feeding your baby.

Tell your doctor if you have any wounds or damaged skin in your ear canal if your Doctor prescribed Soframycin to treat an ear infection.
Antibiotics belonging to the aminoglycoside class may cause permanent loss of hearing or deafness in some cases when it has been applied to open wounds or damaged skin in the ear.

Taking other medicines

Tell your doctor or pharmacist 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

How much to use

Follow all directions given to you by your doctor or pharmacist carefully.
They may differ from the information contained in this leaflet.

Usually, Soframycin should be used as follows:

Remove the cap from the bottle immediately before use and place it back on the bottle immediately after use.

- **For the eye**
  2 drops every one or two hours initially, diminishing to 2 or 3 drops three times daily.
- **For the ear**
  2 or 3 drops may be instilled into the ear three times daily.

How to use it

Soframycin Drops for the ear may be used following the steps below:

1. Wash your hands well with soap and water.
2. Shake the bottle.
3. Remove the lid.
4. To use the drops, tilt your head so that the affected ear is uppermost.
5. Position the rubber dropper, which is attached to the bottle, directly above the ear hole.
6. With the bottle tipped upside down, gently squeeze the rubber dropper until 2 or 3 drops fall into the ear.
7. Keep your head tilted for about a minute to allow the drops to penetrate deep into the ear.
8. Replace the lid, sealing it tightly.
9. Wash your hands again with soap and water to remove any residue

Soframycin Drops for the eye may be used following the steps below:

You may find it easier to put drops in your eye while you are sitting or lying down.

1. Wash your hands well with soap and water.
2. Shake the bottle.
3. Remove the lid.
4. Hold the bottle upside down in one hand between your thumb and middle finger.
5. Using your other hand, gently pull down your lower eyelid to form a pouch.
6. Tilt your head back and look up.
7. Put the tip of the bottle close to your eye. Do not let it touch your eye.
8. Release one drop into your eye by gently squeezing/tapping or pressing the base of the bottle with your index finger.
9. Close your eye. Do not blink or rub your eye.
10. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about 2 minutes. This will help stop the medicine draining through the tear duct to the nose or throat, from where it can be absorbed into other parts of your body. Ask your doctor or pharmacist for more specific instructions on this technique.
11. Repeat steps 4-10 to instil the second drop or follow the directions given to you by your doctor and pharmacist.
12. Replace the lid, sealing it tightly.
13. Wash your hands again with soap and water to remove any residue.

If you are not sure how to use eye drops, ask your doctor or pharmacist.

How long to use it

Continue using Soframycin 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

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using Soframycin.

Wait at least 15 minutes before reinserting contact lenses after you have used Soframycin in the eyes. One of the ingredients in Soframycin is known to discolour soft contact lenses.

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

Things you must not do

Do not give Soframycin to anyone else, even if they have the same condition as you.

Do not use Soframycin to treat any other complaints unless your doctor or pharmacist tells you to.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Soframycin.

Although most people will not experience a side effect, Soframycin has been known to cause allergic reactions.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Itching or redness of the eyes or ears

After using it

Storage

Keep your medicine in a cool, dry place where the temperature stays below 25°C. Do not refrigerate.

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

Soframycin should be discarded 4 weeks after first opening.

If your doctor or pharmacist tells you to stop using Soframycin or the medicine has passed the 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

Soframycin Eye/Ear Drops is a sterile colourless solution in an amber glass dropper bottle. Each bottle contains 8 mL of solution.

Ingredients

Soframycin does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Soframycin Eye/Ear Drops contains:

Active ingredient:

- framycetin sulfate (5 mg/mL)

Inactive ingredients:

- citric acid - anhydrous
- sodium citrate
- sodium chloride
- benzalkonium chloride (preservative)
- water - purified

Supplier

Soframycin is supplied in Australia by:

sanofi-aventis Australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113
Freecall No: 1800 818 806

Soframycin is supplied in New Zealand by:

sanofi-aventis New Zealand limited
Level 8
56 Cawley Street
Ellerslie, Auckland
Freecall No:0800 283 684

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