

Soframycin®

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 Soframycin?

Soframycin contains the active ingredient framycetin sulfate. Soframycin is used to treat bacterial infection of the eye or ear.

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

2. What should I know before I use Soframycin?

Do not use if you have ever had an allergic reaction to Soframycin 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 Soframycin?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Soframycin 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 Soframycin?

- 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.

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

5. What should I know while using Soframycin?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit 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 should not do	<ul style="list-style-type: none">• Do not stop using Soframycin, or lower the dosage, without checking with your doctor or pharmacist.• Do not use Soframycin to treat any other complaints unless your doctor or pharmacist tells you to.
Looking after your medicine	<ul style="list-style-type: none">• Keep Soframycin in a cool dry place where the temperature stays below 25°C. Do not refrigerate.

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

6. Are there any side effects?

Side effects include itching or redness of the eyes or ears.

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.

Soframycin®

Active ingredient: framycetin sulfate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Soframycin. **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 Soframycin.**

Where to find information in this leaflet:

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

1. Why am I using Soframycin?

Soframycin contains the active ingredient framycetin sulfate. Soframycin is an antibiotic of the aminoglycoside class. It works by killing bacteria.

Soframycin is used to treat bacterial infection of the eye or ear.

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.

2. What should I know before I use Soframycin?

Warnings

Do not use Soframycin:

- If you are allergic to framycetin sulfate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- In your ear if you have a hole in your eardrum (tympanic membrane).
- if you are pregnant or intend to become pregnant.
- 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.
- 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

Check with your doctor if you:

- have allergies to antibiotics, especially framycetin.
- take any medicines for any other condition, especially antibiotics such as neomycin, paromomycin and kanamycin.
- have allergies to any other substances, such as foods, preservatives or dyes.

- 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.

- 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.

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 Soframycin if you are pregnant or intend to become pregnant.

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

Like most medicines of this kind, Soframycin 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. It is not known whether Soframycin may affect your developing baby if you use while breast feeding your baby.

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 Soframycin.

4. How do I use Soframycin?

How much to use

Follow the instructions provided when Soframycin was prescribed, including the number of days it should be taken. 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 Soframycin

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 Soframycin

Soframycin 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 Soframycin

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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 - Australia - or 0800 764 766 - New Zealand), 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 Soframycin?

Things you should 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.

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

Things you should 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

Looking after your medicine

- Keep your medicine 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.

When to discard your medicine

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.

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.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Itching or redness of the eyes or ears 	<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 (Australia) or to in New Zealand at <https://nzphvc.otago.ac.nz/reporting>. 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 Soframycin contains

Active ingredient (main ingredient)	framycetin sulfate (5 mg/mL)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • citric acid monohydrate • sodium citrate dihydrate • sodium chloride • benzalkonium chloride (preservative) • water for injections
Potential allergens	<ul style="list-style-type: none"> • benzalkonium chloride (preservative)

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

What Soframycin looks like

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

(Aust R 47541).

Who distributes Soframycin

Distributed in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

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Sylvia Park Auckland 1644

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