

WAXSOL[®] Ear Drops

Active ingredient: docusate sodium 0.5% w/v

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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1. Why am I using WAXSOL?

WAXSOL contains the active ingredient docusate sodium. WAXSOL is used to help remove ear wax in adults, and the elderly. Use in children under 12 years only on medical advice. The drops help to clear your ear canal if it is blocked with wax by softening it and breaking it up. WAXSOL contains a mild emulsifier which penetrates and helps disperse ear wax.

What is ear wax?

Ear wax is produced by the glands in the skin lining the ear canal, and its purpose appears to be protective.

Ear Care

The shape of the ear canal makes it difficult to clean. Because of the delicate nature of the ear, cotton buds and other instruments should never be inserted into it. WAXSOL is used to soften and remove the ear wax.

2. What should I know before I use WAXSOL?

Warnings

Do not use WAXSOL if:

- you have hypersensitivity to the active substance, to any of the excipients, or components that form the finished product (see list in Section 6 Product Details).

Always check the ingredients to make sure you can use this medicine.

- you have a perforated ear drum (a hole in your eardrum)
- your ear is sore or inflamed

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 [5. Are there any side effects?](#)

Pregnancy and breastfeeding

WAXSOL can be used if you are pregnant or breastfeeding.

3. How do I use WAXSOL?

How much to use

- **Always use WAXSOL exactly as directed.**

You should check with your doctor or pharmacist if you are not sure.

How to use the drops:

- Fill the dropper from the bottle.
- Tilt your head to one side.
- Gently drip WAXSOL into your blocked ear until it is full.
- Place a cotton wool plug in the ear. The best time to do this is before you go to bed.
- **Only use the drops for 2 nights at a time.**

If you feel the drops are not working after this time, or the problem continues to exist, please contact your doctor or pharmacist.

If you use too much WAXSOL

If you use more WAXSOL than you should, this may seep from the ear.

It is unlikely that you will notice any problems but if you do have any, (such as skin irritation), you should tell your doctor.

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

4. What should I know while using WAXSOL?

Things you should do

Do not use WAXSOL if you have an injury or swelling of the ear canal as this may result in painful symptoms. Always tell your doctor or pharmacist if you think the drops are causing you a problem.

Driving or using machines

WAXSOL has no or negligible influence on the ability to drive and use machines. However, if dizziness occurs, driving and using machines should be avoided.

Looking after your medicine

- Store the bottle below 25°C.
- Use only if cap seal is intact.

Keep it where young children cannot reach it.

When to discard your medicine

Discard after 4 weeks of first opening the bottle.

Getting rid of any unwanted medicine

Do not use WAXSOL after the expiry date which is printed or embossed on the carton and label.

5. Are there any side effects?

Like all medicines, WAXSOL can cause side effects, although not everybody gets them.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">Application site reactions e.g. pain, irritation, redness, itching, inflammation or peeling of the skinInfection of the outer ear and ear canal involving a lot of pain and rednessDizziness, reduced hearing ability or ear discomfort	Tell your doctor as soon as possible if you notice any of the following

Serious side effects

Serious side effects	What to do
Some people may have an allergic reaction (possibly delayed) which may include but is not limited to the following: <ul style="list-style-type: none">redness of the skin area and/or a rash orallergic reaction to the latex in the dropper applicator, which can be severe including difficulty breathing or fainting	Seek urgent medical advice if you experience an allergic reaction

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.

6. Product details

This medicine is available over-the-counter without a doctor's prescription.

What WAXSOL contains

Active ingredient (main ingredient)	10 mL of docusate sodium 0.5% w/v in a water miscible base containing glycerine and water
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Other ingredients (inactive ingredients)	hydroxybenzoate esters 1.7 mg/mL and phenoxyethanol 4.3 mg/mL as preservatives Disodium phosphate dihydrate Citric acid monohydrate
Potential allergens	Contains 2-phenoxyethanol and hydroxybenzoates as preservatives. Contains sulfites. The dropper applicator contains latex.

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

What WAXSOL looks like

WAXSOL is a clear colourless liquid.

Who distributes WAXSOL

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel St
Cremorne VIC 3121
www.arrotex.com.au

Arrotex Pharmaceuticals (NZ) Limited
C/o Quigg Partners
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Wellington 6011

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