

Package leaflet: Information for the user

WAXSOL 0.5% W/V EAR DROPS SOLUTION Docusate Sodium

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any Possible side effects not listed in this leaflet.

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1. What WAXSOL is and what it is used for

WAXSOL is used to help remove ear wax in adults, the elderly and children. The drops help to clear your ear canal if it is blocked with wax by softening it and breaking it up.

2. What you need to know before you use WAXSOL

Do not use WAXSOL:

- If you are allergic (hypersensitive) to docusate sodium or any of the other ingredients of WAXSOL.
- if you have a perforated (burst) ear drum
- if your ear is sore inside

Warnings and Precautions

Talk to your doctor or pharmacist before using WAXSOL.

- If pain or inflammation is experienced treatment should be discontinued
- As WAXSOL contains parahydroxybenzoates, allergic reactions (possibly delayed) may be experienced.

Other medicines and WAXSOL

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine

- WAXSOL can be used if you are pregnant or thinking of becoming pregnant
- Waxesol can be used if you are breastfeeding

Driving and using Machines

WAXSOL should not affect your ability to drive or use machines.

3. How to use Waxsol

Always use WAXSOL exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

Adults (including the elderly):

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.

The best time to do this is before you go to bed.

Children (6-12 years): As for the adult dose

Only use the drops for 2 nights at a time. If you feel that the drops are not working after this time, or the problem continues to exist, please contact your doctor or pharmacist.

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 any further questions on the use of the product, ask your doctor or pharmacist.

4. Possible Side Effects

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

- Some people may have an allergic reaction which may include redness of the skin area and/or a rash.
- Rarely there is stinging or soreness, which does not last long. If it does continue, do not use the drops on the next night.
- Injuries or swelling of the ear canal may result in painful symptoms.

Always tell your doctor or pharmacist if you think the drops are causing you a problem. If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store WAXSOL

Keep all medicines out of the sight and reach of children.

Do not store above 25 °C.

Do not use WAXSOL after the expiry date which is printed or embossed on the carton and label as month/year. The expiry date refers to the last day of that month. Once opened, do not use after four weeks after the first date of opening.

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 WAXSOL contains

The active substance is Docusate sodium. The liquid in the bottle contains 0.5 % w/v docusate sodium.

The other ingredients are glycerol, purified water and a preservative called phenonip (Phenonip contains phenoxyethanol, ethyl parahydroxybenzoate (E 214), n-butyl parahydroxybenzoate, methyl parahydroxybenzoate (E218), n-propyl parahydroxybenzoate (E 216), iso-butyl parahydroxybenzoate)

What WAXSOL looks like and contents of the bottle

WAXSOL is a clear, colourless liquid and is available in 10 millilitre amber glass bottles which contain a special dropper.

Marketing Authorisation Holder

The Marketing Authorisation holder is
Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoyle Industrial Estate,
Dublin 13,
Ireland.

Manufacturer;

The manufacturer is:

Norgine Pharma, 29 Rue Ethé-Virton, 28100 Dreux, France

Ear care

Your ears normally look after themselves. Never put cotton buds or anything else inside your ear. You could hurt yourself.

The ears make wax naturally. Sometimes it builds up and goes hard. When this happens you may become a bit deaf, or have earache.

You can use Waxsol Ear Drops on their own or before the doctor or nurse washes out your ear. Never put anything in your ear to try and clear the wax yourself.

This leaflet was last reviewed in December 2018