

PACKAGE LEAFLET: INFORMATION FOR THE USER

WAXSOL EAR DROPS

Docusate Sodium BP 0.5% w/v

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.
- Ask your pharmacist if you need more information or advise.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

If you need the information on this leaflet in an alternative format, such as large text, or Braille please ring from the UK: 0800 198 5000.

In this leaflet:

1. What WAXSOL is and what it is used for
2. What you need to know before you use WAXSOL
3. How to use WAXSOL
4. Possible side effects
5. How to store WAXSOL
6. Contents of the pack and other information

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 to docusate sodium or any of the ingredients of this medicine (listed in section 6).
- if you have a perforated (burst) eardrum.
- if your ear is sore inside.

Warning and precautions

Talk to your doctor or pharmacist or nurse before using Waxsol
Discontinue the treatment if you experience pain or inflammation.

Taking or using other medicines

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 breastfeeding

- If you are pregnant or thinking of becoming pregnant WAXSOL can be used.
- If you are breast-feeding WAXSOL can be used.

Driving and using Machines

WAXSOL should not affect your ability to drive or use machines. However, if dizziness occurs, driving and using machines should be avoided.

Waxsol contains parabens

Parabens may cause allergic reactions (possibly delayed).

The dropper applicator of this medicinal product contains latex rubber. May cause severe allergic reactions.

3. How to use WAXSOL

Always use WAXSOL exactly as your doctor has told you.

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 10 drops of WAXSOL into your blocked ear or until it is full.
- Plug the ear using cotton wool, leaving in the ear overnight.

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

Do not use for more than 2 consecutive nights.

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 this product, ask your doctor or pharmacist.

4. Possible side effects

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

Frequency not known

- Inflammation of the external ear canal
- Some people may have an allergic reaction which may include redness of the skin area and/or a rash, irritation and exfoliation
- Dizziness
- Hearing loss, Ear pain, ear discomfort

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA yellow card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store WAXSOL

Keep this medicine out of the sight and reach of children.

Store the bottle below 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 from the first date of opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Content of the pack and other 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, citric acid monohydrate, disodium phosphate dihydrate, water and a preservative called phenonip.

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 Products Ltd., Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturer:

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 on its 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 revised in Nov 2022.