

## **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.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. 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.

**What is in this leaflet:**

- 1. What WAXSOL is and what it is used for**
- 2. What you need to know before you use Waxesol**
- 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 contains the active substance docusate sodium. 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 (listed in section 6).
- if you have a perforated (burst) ear drum
- if your ear is sore inside

#### **Warnings and Precautions**

If you have pain or inflammation while using WAXSOL, treatment should be stopped.

#### **Other medicines and WAXSOL**

Please tell your doctor or pharmacist if you are taking, have recently taken or might take 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
- WAXSOL can be used if you are breastfeeding

#### **Driving and using Machines**

WAXSOL should not affect your ability to drive or use machines. However, if you have dizziness, do not drive or operate machines.

### **WAXSOL contains parahydroxybenzoates**

Parahydroxybenzoates may cause allergic reactions (possibly delayed).

The dropper provided with WAXSOL contains **latex rubber**, which may cause severe allergic reactions.

### **3. How to use Waxsol**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist 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, e.g. usually 10 drops.
- Plug the ear using cotton wool, leaving in the ear overnight.

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.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Other possible side effects (frequency cannot be estimated from the available data):

- Redness and swelling (inflammation) of the external ear canal, which is the tube between the outer ear and eardrum
- Dizziness
- Loss of hearing
- Pain or discomfort in the ear
- Allergic skin reaction (which may include redness of the skin area and/or a rash).
- Soreness, itching, skin shedding (exfoliation), redness and swelling (inflammation), pain, or redness of the skin at the area where the drops are applied, which does not last long. If it does continue, do not use the drops on the next night.

Always tell your doctor or pharmacist if you think the drops are causing you a problem.

### **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, Website: [www.hpra.ie](http://www.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, disodium phosphate dihydrate, citric acid monohydrate, 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 with a dropper applicator (polypropylene screw cap and pipette, natural rubber bulb).

#### **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 July 2022