

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Ear Wax Remover Drops

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Docusate Sodium BP 5.0% w/v

### **3 PHARMACEUTICAL FORM**

Ear Drops, solution.

A clear, colourless, viscous liquid, odourless or almost odourless.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

For the softening of ear wax to facilitate its removal.

#### **4.2 Posology and method of administration**

##### Adults:

Four drops to be instilled into the affected ear or ears twice daily for 2-3 days. The head should be inclined and the ear plugged with cotton wool, soaked in ear wax remover drops if necessary.

After 2-3 days the wax should be easy to remove.

##### Children:

The number of drops instilled may be reduced to the level required to fill the ear with solution.

##### Elderly:

No dosage adjustments are necessary.

### **4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Not to be used if the ear drum is known or suspected to be perforated; or if there is an inflammation of the ear.

### **4.4 Special warnings and precautions for use**

If pain or inflammation is experienced, treatment should be discontinued.  
The dropper unit of this medicinal product contains latex rubber. May cause severe allergic reactions.

### **4.5 Interaction with other medicinal products and other forms of interaction**

None known.

### **4.6 Fertility, pregnancy and lactation**

There is no evidence to suggest that ear wax remover drops should not be used during pregnancy and lactation.

### **4.7 Effects on ability to drive and use machines**

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

### **4.8 Undesirable effects**

Evaluation of undesirable effects is based on the following frequency information:

- Very common ( $\geq 1/10$ )
- Common ( $\geq 1/100$  to  $< 1/10$ )
- Uncommon ( $\geq 1/1,000$  to  $< 1/100$ )
- Rare ( $\geq 1/10,000$  to  $< 1/1,000$ )
- Very rare ( $< 1/10,000$ )
- Not known (cannot be estimated from the available data)

**Infections and infestations**

Frequency not known: Otitis externa

**Immune system disorders**

Frequency not known: hypersensitivity/allergic reactions

**Nervous system disorders**

Frequency not known: Dizziness

**Ear and labyrinth disorders**

Frequency not known: Hypoacusis, ear pain, ear discomfort

**Skin and subcutaneous tissue disorders**

Frequency not known: Allergic skin reactions, contact dermatitis

**General disorders and administration site conditions**

Frequency not known: Application site reactions (e.g. irritation, pruritus, exfoliation, inflammation, pain, erythema).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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.

**4.9 Overdose**

Excess Ear Wax Remover Drops may seep from the ear and treatment of any resulting adverse events, such as skin irritation, should be symptomatic.

**5 PHARMACOLOGICAL PROPERTIES****5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Other otologicals, ATC code: S02DC

Docusate sodium is a cerumenolytic substance; its emulsifying action softens the ear wax plug.

Ear wax is produced by the glands in the skin lining of the ear canal, and its purpose appears to be protective. Occasionally ear wax can build up and harden in the ear, causing problems if not removed. Excessive amounts of hardened ear wax can cause poor hearing, ringing in the ears or earache.

The so-called “wax” which often obstructs the external auditory meatus of the ear contains less than 50% of fatty matter derived from secretions of the sebaceous ceruminous glands. The majority of the wax consists of desquamated epithelium, foreign matter and shed hairs. This non-fatty material forms a matrix holding together the granules of fatty matter to form the ceruminous mass.

The addition of oils or solvents binds the mass more firmly together, but aqueous solutions, if they are able to penetrate the matrix, cause a disintegration of the ceruminous mass.

Ear Wax Remover Drops, because of their low surface tension and miscibility, rapidly penetrate the dry matrix of the ceruminous mass, reducing the solid matter to a semisolid debris. This can be syringed away readily, or in less severe or chronic cases, is ejected by normal physiological processes.

## **5.2 Pharmacokinetic properties**

There are no available data on systemic absorption following instillation into the ear.

However, any absorption which may occur is likely to be of an extremely low magnitude.

## **5.3 Preclinical Safety Data**

Although no toxicity studies via application to the ear are available, oral repeated dose toxicity studies with docusate sodium did not identify any clinically relevant information.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Polyethylene Glycol 400 HSE

## **6.2 Incompatibilities**

None known.

## **6.3 Shelf life**

18 months

**6.4 Special precautions for storage**

None.

**6.5 Nature and contents of container**

Amber glass bottle with removable glass dropper unit.

**6.6 Special precautions for disposal**

Amber glass bottle with removable glass dropper unit.  
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7 MARKETING AUTHORISATION HOLDER**

Bell, Sons & Co (Druggists) Limited,  
Gifford House,  
Slaidburn Crescent,  
Southport,  
Merseyside,  
PR9 9AL,  
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**8 MARKETING AUTHORISATION NUMBER(S)**

PL 03105/0108

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

11/01/2012

**10 DATE OF REVISION OF THE TEXT**

08/03/2024