SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Molcer Ear Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Docusate Sodium 5.0% w/v

Excipients with known effects:
Propylene Glycol

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ear Drops, Solution

A water white liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the softening of ear wax, prior to syringing with warm water.

4.2. Posology and Method of Administration

Adults, children and the elderly:

Lie on side with the affected ear uppermost. Fill the ear with Molcer Ear Drops using the dropper and remain in this position for a few minutes. Place a small plug of cotton wool in the ear before rising and leave the plug in until the next treatment. If both ears are affected repeat the procedure for the other ear. Do this for two nights and the wax will be soft and easily removed.

In difficult cases it may be necessary for you doctor to employ syringing with warm water to remove the wax after it has been softened.

4.3 Contraindications

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

Contraindicated for use in patients with the following conditions:
Tympanic performance, Eczematous, otitis extema, other inflammatory or infective conditions of the external auditory meatus.

4.4 Special warnings and precautions for use

This medicine contains 468mg Propylene Glycol in each 1ml.

Propylene glycol may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, pregnancy and lactation

Molcer Ear Drops can be used during pregnancy and breast-feeding.

4.7 Effects on ability to drive and use machines

Molcer Ear Drops has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

System Organ Class	Very Common (≥1/10)	Common ≥1/100, < 1/10	Uncommon ≥1/1,000, <1/100	Rare ≥1/10,000, <1/1000	Very Rare <1/10,000	Not known (cannot be estimated from available data)
Immune system disorder						Hypersensitivity (local)

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: Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Emollients and Protectives
ATC Code: D02AX
Docusate sodium is an anionic surfactant. It has a direct action on hardened ear wax, gradually softening it.

5.2. Pharmacokinetic Properties

Docusate Sodium acts directly on the hardened ear wax softening it over the period of a few days. There is negligible systemic absorption when used as directed.

5.3. Preclinical Safety Data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol and Purified Water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf Life

36 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Amber glass vial of 15ml supplied with dropper.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Wallace Manufacturing Chemists Ltd.
Wallace House
51-53 Stert Street
Abingdon
Oxfordshire OX14 3JF
United Kingdom

8. MARKETING AUTHORISATION NUMBERS

PL 0400/5019R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

18 September 1990, 16 July 1996

10 DATE OF REVISION OF THE TEXT

25/04/2023