Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

WAXSOL 0.5% w/v Ear Drops Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

WAXSOL Ear Drops contain the following active ingredient:

Docusate Sodium 0.5% w/v.

Excipients with known effect: parahydroxybenzoates max 0.6% w/v.

For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Ear drops, solution (Ear Drops)

A clear colourless liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

WAXSOL Ear Drops are indicated as an aid in the removal of ear wax.

4.2 Posology and method of administration

For aural use only.

Posology:

Adults (including the elderly): The application of ear drops sufficient to fill the affected ear, e.g. usually 10 drops.

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

Method of Administration:

Apply before going to bed, tilt the head and fill the ear canal with WAXSOL Ear Drops. Plug the ear using cotton wool, leaving in the ear overnight. The softened earwax should come out of the ear without requiring syringing. If the problem persists patients should consult their doctor.

Do not apply for more than 2 consecutive nights.

4.3 Contraindications

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

Perforation of the ear drum or inflammation of the ear.

4.4 Special warnings and precautions for use

If pain or inflammation is experienced, treatment should be discontinued.

WAXSOL Ear Drops contains parahydroxybenzoates, which may cause allergic reactions (possibly delayed).

The dropper applicator 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 WAXSOL Ear Drops should not be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

WAXSOL Ear Drops 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

Tabulated summary of adverse reactions

The frequency of adverse reactions is defined using the following convention:

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

System Organ Class	Frequency	Adverse Reaction
Infections and infestations	Not known	Otitis externa
Immune system disorders	Not known	Hypersensitivity/allergic reactions
Nervous system disorders	Not known	Dizziness
Ear and labyrinth disorders	Not known	Hypoacusis, ear pain, ear discomfort
Skin and subcutaneous tissue disorders	Not known	Allergic skin reactions, contact dermatitis
General disorders and administration site conditions	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 HPRA Pharmacovigilance, Website: www.hpra.ie

4.9 Overdose

Excess WAXSOL Ear Drops may seep from the ear and the 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.

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.

Ear wax 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.

WAXSOL Ear Drops, because of their low surface tension and miscibility, rapidly penetrate the dry matrix of the ceruminous mass, reducing the solid material to a semi-solid 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

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Disodium phosphate dihydrate
Citric acid monohydrate
Phenonip*
Purified Water
*Phenoxyethanol
ethyl parahydroxybenzoate (E214)
n butyl parahydroxybenzoate
methyl parahydroxybenzoate (E218)
n propyl parahydroxybenzoate (E216)
and iso butyl parahydroxybenzoate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 18 months
Opened: 4 weeks

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

Amber glass bottle of 10ml capacity with a dropper applicator (polypropylene screw cap and pipette, natural rubber bulb).

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Cooper Consumer Health B.V.
Verrijn Stuartweg 60
Diemen
Noord-Holland
1112 AX
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA25506/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

January 2026