1. NAME OF THE MEDICINAL PRODUCT

WAXSOL Ear Drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

WAXSOL Ear Drops contain the following active ingredient:

Docusate Sodium BP 0.5% w/v.

Excipient(s) with known effect: Parabens
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ear drops, solution.
A clear colourless liquid

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.

Recommended dose and dosage schedules:

Adults and elderly
Usually 10 drops per ear / sufficient to fill the affected ear.

Paediatric population
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. Contra-indications

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 parabens. Parabens may cause allergic reactions (possibly delayed).

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

4.5. Interactions 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

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 (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

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

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.

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.

WAXSOL Ear Drops, because of their low surface tension and miscibility, rapidly penetrate the dry matrix of the ceruminous mass, reducing the solid matter 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. Pre-clinical 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

Citric acid monohydrate

Disodium phosphate dihydrate

Glycerol

Phenonip (solution of esters of 4-hydroxybenzoic acid in phenoxetol)

Water

6.1. Incompatibilities

None known.

6.3 Shelf life

Unopened:18 months

Once opened, do not use after four weeks from the first date of opening.

6.2. Special precautions for storage

Store below 25□.

6.5 Nature and contents of container

Amber glass bottle with a dropper applicator, containing 10ml of solution.

6.3. Special precautions for disposal and other handling

The dropper applicator must be filled before dripping WAXSOL Ear Drops into the affected ear.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PL 46302/0146

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

27/09/2006

10 DATE OF REVISION OF THE TEXT

31/01/2023