Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Exterol 5% w/w Ear Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Urea hydrogen peroxide 5.0% w/w.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ear drops, solution (Ear drops)
Clear, straw-coloured, viscous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an aid in the removal of hardened wax.

4.2 Posology and method of administration

For adults (including the elderly) and children:

Instill up to 5 drops into the ear. Retain drops in ear for several minutes by keeping the head tilted and then wipe away any surplus.

Repeat once or twice daily for at least 3 to 4 days, or as directed by the physician.

4.3 Contraindications

Do not use if the eardrum is known or suspected to be damaged, in cases of dizziness, or if there is any other ear disorder (such as pain, discharge, inflammation, infection or tinnitus).
Do not use after syringing or after ill-advised attempts to dislodge wax using fingernails, cotton buds or similar implements, as such mechanical efforts can cause the ear's delicate inner lining to become damaged, inflamed or infected, whereupon the use of ear drops can be painful.
Do not use where there is a history of ear problems, unless instructed to do so by a doctor.
Do not use if sensitive to any of the ingredients.

4.4 Special warnings and precautions for use

Keep Exterol away from the eyes.
As with all medicines, keep out of the sight and reach of children.
For external use only.
Replace cap after use and return bottle to carton.

4.5 Interaction with other medicinal products and other forms of interaction

Exterol should not be used at the same time as any other type of topical preparation in the ear.

4.6 Fertility, pregnancy and lactation

No known side effects.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Due to the release of oxygen, patients may experience a mild, temporary effervescence in the ear. Stop usage if irritation or pain occurs.
Instillation of ear drops can aggravate the painful symptoms of excessive ear wax, including some loss of hearing, dizziness and tinnitus. Very rarely, blurred vision and unpleasant taste have been reported. If patients encounter any of these problems, or if their symptoms persist or worsen, they should discontinue treatment and consult a doctor.

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

No adverse effects.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

After insertion of the drops into the ear, the urea hydrogen peroxide complex liberates oxygen which acts to break up the hardened wax. The hydrogen peroxide component is also a cerumenolytic. Its action as an antiseptic, especially in sites with relative anaerobiosis, is well known. The glycerol and urea assist in softening the wax, so that it may more easily be removed from the ear, either with or without syringing. The urea acts as a mild keratolytic, helping to reduce the keratin-load in the wax debris, thereby assisting penetration of the other components.

5.2 Pharmacokinetic properties

Exterol is intended only for the treatment of impacted wax in the external auditory canal. The ingredients of the formulation are therefore readily available for intimate contact with the affected area, as the drops are instilled into the ear and retained therein for several minutes by tilting the head.

5.3 Preclinical safety data

No special information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

8-hydroxyquinoline
Glycerol

6.2 Incompatibilities

Do not use concurrently with anything else in the ear.

6.3 Shelf life

Unopened: 18 months.
Discard 4 weeks after first opening.

6.4 Special precautions for storage

Store upright. Store below 25°C.
Keep the bottle tightly closed. Keep the bottle in the outer carton.

6.5 Nature and contents of container

a) Type 1 amber glass bottle incorporating a specially designed polyethylene nozzle applicator enclosed in a polypropylene screw cap, containing 8 ml or 12 ml.
b) Low density polyethylene bottle, with low density polyethylene nozzle applicator and tamper-evident polypropylene screw cap, containing 8 ml or 12 ml.
Not all pack sizes may be marketed.

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

Dermal Laboratories (Ireland) Limited
38 Main Street
Swords
Co Dublin
K67 E0A2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23128/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 February 1982

Date of last renewal: 28 January 2007

10 DATE OF REVISION OF THE TEXT

September 2024