Otex Ear Drops

Summary of Product Characteristics Updated 22-Feb-2021 | Diomed Developments Limited

1. Name of the medicinal product

Otex

2. Qualitative and quantitative composition

Urea hydrogen peroxide 5.0% w/w

For excipients, see 6.1.

3. Pharmaceutical form

Ear drops

Clear, straw coloured viscous ear drops.

4. Clinical particulars

4.1 Therapeutic indications

As an aid in the removal of hardened ear wax.

4.2 Posology and method of administration

For adults, children and the elderly:

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 required.

4.3 Contraindications

Do not use if the eardrum is known or suspected to be damaged, in cases of dizziness, or if there is, or has been, any other ear disorder (such as pain, discharge, inflammation, infection or tinnitus).

Do not use 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. For similar reasons, it is inadvisable to use Otex within 2 to 3 days of syringing.

Do not use where there is a history of ear problems, unless under close medical supervision.

Do not use if sensitive to any of the ingredients.

4.4 Special warnings and precautions for use

Keep Otex away from the eyes.

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

Otex should not be used at the same time as anything else 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, unpleasant taste has 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 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

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 also acts as a mild keratolytic, helping to reduce the keratin-load in the debris. With less debris, the other components are able to reach the skin under the debris and exert their action.

5.2 Pharmacokinetic properties

Otex 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

None known.

6.3 Shelf life

24 months. Discard 4 weeks after first opening.

6.4 Special precautions for storage

Store upright in a cool place and keep out of sunlight.

Store below 25°C.

Replace cap after use.

6.5 Nature and contents of container

a) 12 ml amber glass bottle incorporating a specially designed polythene pipette applicator enclosed in a polypropylene screw cap.

b) 15 ml low density polyethylene bottle with low density polyethylene nozzle applicator and tamper-evident screw cap.*

c) 5 ml low density polyethylene bottle with low density polyethylene nozzle applicator and tamper-evident screw cap.*

* Plus intervening bottle capacities within the range 5 ml to 15 ml, all of exactly the same material.

Supplied as original packs (OP).

6.6 Special precautions for disposal and other handling

Not applicable

7. Marketing authorisation holder

Diomed Developments Limited

T/A Dermal Laboratories

Tatmore Place

Gosmore

Hitchin

Hertfordshire SG4 7QR

England

8. Marketing authorisation number(s)

PL 00173/0151

9. Date of first authorisation/renewal of the authorisation

29 October 1992/Unlimited validity (granted 22/07/2010 for 24/06/2007 renewal date)

10. Date of revision of the text

04/02/2021

Company Contact Details

Diomed Developments Limited

Address

Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR

WWW

www.diomedgroup.co.uk

Telephone

+44 (0)1462 458 866