

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Earex Ear Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Almond Oil	33.33	% v/v
Arachis Oil (peanut oil)	33.33	% v/v
Rectified Camphor Oil	33.33	% v/v

3 PHARMACEUTICAL FORM

Ear drops, solution

Clear, yellow oily liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the easy removal of ear wax.

4.2 Posology and method of administration

Adults, children and the elderly:

1. Incline the head to one side.
2. Insert four drops with the applicator supplied.
3. Insert a piece of cotton wool.
4. Repeat night and morning for up to four days until wax is cleared.

Route of administration: Installation into the ear.

4.3 Contraindications

Use in the presence of inflammation or infection of the ear or nasopharynx.

Use in the presence of a perforated ear drum.

4.4 Special warnings and precautions for use

Never use force or instruments in the ear. Violent nose blowing should always be avoided. Wisdom or any decayed teeth should be examined in all cases of ear trouble.

If there are no improvements consult the doctor.

Earex Ear Drops contain Arachis oil (peanut oil) and should not be applied by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid Earex Ear Drops.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No special precautions.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

None stated.

4.9 Overdose

Unlikely with this dosage form. Gastric lavage may be used in cases of accidental ingestion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Carton containing an amber glass bottle, with a dropper applicator consisting of a polypropylene or urea formaldehyde closure and a soda glass dropper with a butyl or nitrile rubber teat.

Contents: 10 ml of ear drops.

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

Pharmalab Ltd
Tubiton House
Oldham
OL1 3HS
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8 MARKETING AUTHORISATION NUMBER

PA 547/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 August 1992

Date of last renewal: 19 August 2002

10 DATE OF REVISION OF THE TEXT

July 2005