

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cerumol Ear Drops Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Arachis Oil (Peanut Oil)	57.3	% w/v
Chlorobutanol (Chlorbutol)	5.0	% w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ear Drops, solution
Oily Solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For use in softening and mobilising wax collection in the external auditory meatus.
(Either a collection of soft wax or a harder wax plug).

4.2 Posology and method of administration

At home: With the head inclined, 5 drops are put into the ear. This may cause a harmless tingling sensation. A plug of cotton wool moistened with Cerumol or smeared with petroleum jelly should then be applied to retain the liquid. One hour later, or the next morning, the plug is removed. The procedure is repeated twice a day for three days; the loosened wax may then come out on its own making syringing unnecessary. If any wax remains the doctor should be consulted so that syringing of the softened residue may be carried out.

At the surgery: If there has been no prior treatment with Cerumol, 5 drops are instilled as described above and left for at least 20 minutes. Then syringing or a probe tipped with cotton wool may be employed.

4.3 Contraindications

Contraindicated in hypersensitivity to arachis (peanut) oil, soya, or any of the other ingredients.
Otitis externa, seborrhoeic dermatitis and eczema affecting the outer ear. Perforated ear drums.

4.4 Special warnings and precautions for use

Not to be taken internally. Do not use for more than three days without consulting your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of Arachis Oil and/or Chlorobutanol in pregnant women. Although the risks cannot completely be excluded, systemic exposure to Arachis Oil and Chlorobutanol is thought to be negligible and the adverse effects during pregnancy are therefore not anticipated.

Lactation

There are no or limited amount of data from the use of Arachis Oil and/or Chlorobutanol in lactating women. Although the risks cannot completely be excluded, systemic exposure of the breastfeeding woman to Arachis Oil and Chlorobutanol is thought to be negligible and the adverse effects on the breastfed newborn/infant are therefore not anticipated.

4.7 Effects on ability to drive and use machines

None known, but the actual wax plug may cause deafness.

4.8 Undesirable effects

The product may cause local irritation, redness or rash.

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 of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2. Tel: +353 1 6764971. Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

As the product is applied topically, overdosage as such is not possible. In the case of accidental ingestion, the amounts of the majority of the ingredients in the bottle are too small to give rise to toxic effects. The 550 mg of Chlorobutanol in the whole bottle might cause excessive sedation in a child.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The drug is applied topically to aid the removal of cerumen. Thus normal pharmacological criteria cannot be applied.

The action is thought to be due to the loosening and lubricating properties of the solvent mixture, rather than its solvent properties. This is intrinsic to the solvent mixture.

Arachis Oil: is an oily substance to aid lubrication of the cerumen plug. (Water based solvents cause swelling of cerumen). It is however too viscous to be used on its own.

Chlorobutanol: This is an anti-bacterial and anti-fungal, but its main purpose in this product is to reduce the viscosity of the mixture, giving better penetrating characteristics to the oil.

5.2 Pharmacokinetic properties

The rate of loosening or dissolution of the cerumen is extremely variable. Trials have shown that Cerumol is the only one of a number of agents that was significantly better than sodium bicarbonate in aiding the removal of wax.*

*J Fraser, J Laryng. and Otology, 1970, 84, (10), 1055.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Oil of turpentine
3-methoxy butyl acetate (butoxyl Hoechst)
o-Dichlorobenzene
p-Dichlorobenzene

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 5 years. Use within 6 months of opening.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

11 ml contained in a 12.5 ml amber glass bottle. Packaged together with a separate dropper.

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

Thornton & Ross Limited
Linthwaite
Huddersfield
HD7 5QH
United Kindgom

8 MARKETING AUTHORISATION NUMBER

PA0610/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 August 1991
Date of last renewal: 26 August 2006

10 DATE OF REVISION OF THE TEXT

March 2016