Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Audax Ear Drops Solution Choline Salicylate 20%w/v Glycerol 12.6%w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Choline Salicylate 20.0%w/v.
Glycerol 12.6%w/v.

Excipients: also contains 1.25%w/v ethylene oxide polyoxypropylene glycol and up to 66.6%w/v propylene glycol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ear drops solution
Clear, faintly tan solution, with a characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For relief of pain in otitis externa and media, furuncles and other local inflammation, softening of earwax and aid to earwax removal.

4.2 Posology and method of administration

Topical into ear.

Place the head on one side with the affected ear uppermost. Completely fill the external auditory canal with drops. The ear should be plugged with cotton wool soaked with the eardrops or a wick may be inserted if preferred. Audax Ear Drops should be instilled every 3 to 4 hours until permanent relief of symptoms is obtained.

4.3 Contraindications

1. Use in patients hypersensitive to salicylates.
2. Perforated ear drum.

4.4 Special warnings and precautions for use

1. If symptoms persist, the doctor should be consulted.
2. If the patient is under the doctor's care or is on any medication, the doctor should be consulted before using.
3. Contains propylene glycol and esters which may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interactions

None stated.

4.6 Fertility, pregnancy and lactation

There is no known hazard with the use of this product during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

None stated.

4.9 Overdose

Each bottle of Audax Ear Drops contains 1.6g of choline salicylate equivalent to 1.2g of aspirin. Accidental or deliberate ingestion of the contents of a bottle of Audax Ear Drops is therefore only of concern in small infants.

In such cases, signs of intoxification may include dizziness, tinnitus, sweating, vomiting, confusion and hyperventilation. Gross overdosage may lead to central nervous system depression.

Management should include, as appropriate, induced vomiting, correction of fluid and electrolyte balance and measurement of plasma salicylate levels. At concentrations in excess of 300 mg/litre measures such as forced alkaline diuresis and haemodialysis to enhance clearance may be appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Choline salicylate has actions similar to those of aspirin, i.e., analgesic, anti-inflammatory, and anti-pyretic actions considered to be due to inhibition of the biosynthesis of prostaglandins. Glycerol softens ear wax due to its water-retaining and emollient properties.

5.2 Pharmacokinetic properties

Not applicable as Audax Ear Drops are applied topically.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethylene oxide polyoxypropylene glycol
Chlorobutanol hemihydrate
Hydrochloric acid (for pH adjustment)
Propylene glycol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Amber glass bottle (Ph.Eur.Type III), with a polypropylene pipette, containing 8 ml or 10 ml of product.

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

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8 MARKETING AUTHORISATION NUMBER

PA22702/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

June 2019