Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tropex 5% w/v Ear Drops Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of solution contains Phenazone 50mg (5% w/v).

Excipient(s) with known effect
Each ml also contains 1mg methylparahydroxybenzoate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ear drops, solution
Clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the management of the symptoms of otitis media and other inflammatory conditions of the ear. Also for the softening and removal of earwax.

4.2 Posology and method of administration

Route of administration: For auricular use.

Recommended Dosage Schedule:

4-6 drops to be introduced into the ear three to four times a day according to the severity of the inflammation.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1

Tropex should not be used in patients who have perforated eardrums.

4.4 Special warnings and precautions for use

If improvement does not occur within 24 hours the doctor should be consulted.

If infection is present the doctor should be consulted.

4.5 Interaction with other medicinal products and other forms of interactions

Oral phenazone affects the metabolism of drugs broken down by liver enzymes. However, little absorption is expected from topical application into the auditory canal.

4.6 Fertility, pregnancy and lactation

There is no information to contraindicate the use of Tropex during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Phenazone may give rise to skin eruptions and hypersensitivity reactions.

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, 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

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification (Group + ATC code): Analgesic and Antipyretic: S02DA03. Phenazone has analgesic and antipyretic properties. Topically, solutions containing 5% of phenazone have been used locally as ear drops in disorders such as otitis media because of its local anti-inflammatory and analgesic action. Glycerol softens wax.

5.2 Pharmacokinetic properties

Phenazone is readily absorbed from the gastro-intestinal tract and is distributed throughout the body fluids. Peak plasma concentrations are usually obtained in 1 to 2 hours. Less than 10% is bound to plasma proteins and it has a half-life of about 12 hours. Phenazone is metabolised in the liver, about 30% to 40% is metabolised to 4-hydroxyphenazone which is excreted in the urine as the glucuronide. Approximately 5% is excreted unchanged and approximately 6% is norphenazone in the urine.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Methyl parahydroxybenzoate (E218)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.
Do not refrigerate.

6.5 Nature and contents of container

Tropex is filled into 10 ml amber glass bottles equipped with a dropper attachment consisting of a black polyethylene screw cap with a hole in the centre inserted with a red rubber teat. The rubber teat is inserted with a clear glass pipette.

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

Rowa Pharmaceuticals Limited
Newtown
Bantry
Co. Cork
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0074/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 March 1976

Date of last renewal: 24 March 2006

10 DATE OF REVISION OF THE TEXT

January 2020