

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

OTIRELAX (40 mg/10 mg)/1 g, ear drops, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g of solution contains 40 mg of phenazone and 10 mg of lidocaine hydrochloride.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ear drops, solution.

Clear, colourless to slightly brownish-yellow solution, practically free from particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Local symptomatic treatment of certain painful conditions of the middle ear with intact tympanic membrane:

- congestive acute otitis media,
- so-called phlyctenular viral otitis,
- barotrauma otitis.

4.2 Posology and method of administration

In order to avoid unpleasant contact of the cold solution with the ear, warm the container between the hands before use.

- Dropper bottle: instill 4 drops in the auditory meatus of the painful ear, 2 or 3 times a day.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Tympanic perforation of infectious or traumatic origin (see section 4.4 Special warnings and special precautions for use).

4.4 Special warnings and precautions for use

Warnings

As a precautionary measure, ensure that the tympanic membrane is intact before any administration.

If there is tympanic destruction, intra-auricular administration may bring the product into contact with the structures of the middle ear, with adverse effects upon them.

This medicine contains an active ingredient which may give a positive result in the anti-doping tests.

Precautions for use

Limit treatment duration to 10 days. Management must be reviewed after that time.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, pregnancy and lactation

In the absence of any tympanic breach, systemic penetration is unlikely.

As a result, under normal conditions of use, this medicine can, if necessary, be used during pregnancy and lactation.

4.7 Effects on the ability to drive and use machines

OTIRELAX has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions are listed according to MedDRA system organ class and frequency category. Frequency categories are defined using the following convention: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$); not known (cannot be estimated from the available data).

Ear and labyrinth disorders

Rare: local reactions in the form of allergy, irritation or hyperemia of the auditory meatus.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 national reporting system.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Otologicals, analgesics and anesthetics, ATC code: S02DA30.

Phenazone: pyrazolone derivative with analgesic and anti-inflammatory properties.

Lidocaine: local anesthetic of the amide group.

5.2 Pharmacokinetic properties

In view of the route of administration (external use) and the low doses used, a systemic absorption is not envisaged (in the absence of any tympanic breach).

5.3 Preclinical safety data

Not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium thiosulphate

Ethanol 96%

Glycerol

Purified water

Sodium hydroxide 1M (for pH adjustment)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years

Discard within 28 days of first opening.

6.4 Special precautions for storage

Store at temperatures below 25°C.

Store in the original package.

6.5 Nature and content of container

White PE bottle of 15 ml, white PE dropper, non sterile and white screw cap sealed with safety ring.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

ROMPHARM COMPANY SRL

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8. DATE OF REVISION OF THE TEXT

May 2022