ANNEX 1

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Triamcinolone Acetonide ACE 1 mg/mL, acidic ear drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

10 mL acidic ear drops contains 10 mg triamcinolone acetonide

Excipient(s) with known effect: Contains 0.15 mg propylene glycol (E1520) per 3 drops.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ear drops, solution

It is a clear, colourless solution and the solution has a pH of 2.0-4.0.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Triamcinolone acetonide ACE 1 mg/mL, acidic ear drops is indicated for use in adults and children with acute wet otitis externa with severe itching.

4.2 Posology and method of administration

Posology
Adults and children, 3 times daily, 3 drops in the infected ear, unless prescribed otherwise by the doctor. The treatment should generally be continued for 7-14 days.

Before each application, clean the external ear canal and make sure it is dry. Do not use soap, because this can have a negative effect on the acidity.

Method of administration

- Hold the bottle in your hand to bring it to room temperature.
- Tilt your head to the side or lie down on your side. Pull the ear up and back; in children under the age of 6, pull it down and back.
- After administering the drops, keep the head tilted sideways for 2 more minutes.
- After that, you may place a cotton ball in the ear to prevent fluid from trickling out.
- Avoid contact between the dropper and the ear as much as possible to prevent contamination of the drops.
- Close the bottle as soon as you are done applying the drops.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Hypersensitivity to other corticosteroids
- Patients with ear tubes or a perforated eardrum.

4.4 Special warnings and precautions for use

The use of Triamcinolone Acetonide ACE 1 mg/mL, acidic ear drops does not necessarily preclude concomitant systemic or local treatment with antibiotics.

The use of ear drops with acetic acid is contraindicated in patients with a perforated eardrum due to potential ototoxicity.

Symptoms of superinfection and/or hypersensitivity may be masked or exacerbated by corticosteroids. If the patient develops a superinfection, the treatment should be stopped.

If there is no clinical improvement, the treatment should not be continued. Local administration of medicinal products with corticosteroids for a longer period without monitoring by a physician is generally not recommended.

If a hypersensitivity reaction occurs or is suspected during the therapy, the treatment should be stopped.

Propylene glycol may cause a hypersensitivity reaction in susceptible individuals. The therapy should be stopped in that case.

The ear drops contain propylene glycol, which can cause irritation of the skin.

Paediatric population
Absorption through the skin may be increased in newborns and young children, and this may result in adverse reactions.

4.5 Interaction with other medicinal products and other forms of interaction

The available data indicate that Triamcinolone Acetonide ACE 1 mg/mL, acidic ear drops can be used safely in combination other medicinal products, provided it is used for the specified indications and according to the instructions.

4.6 Fertility, pregnancy and lactation

Triamcinolone acetonide ACE 1 mg/mL, acidic ear drops have been used for many years by women who are pregnant or who are breastfeeding, without any evidence of negative effects on the child. Animal studies have shown that corticosteroids are teratogenic. Caution is therefore advised with regard to prolonged use during pregnancy.

4.7 Effects on ability to drive and use machines

Triamcinolone acetonide ACE 1 mg/mL, acidic ear drops has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

There may be hypersensitivity to the ingredients.

The following adverse reactions have been observed:

Ear and labyrinth disorders

- Irritation of the ear (stinging or burning sensation)
- Hypersensitivity reactions (increased itching, redness and swelling)
- Keep in mind that prolonged use may cause thinning of the eardrum and the adverse reactions generally associated with corticosteroids.

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 the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl.

4.9 Overdose

There are no known cases of acute overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: triamcinolone acetonide in combination with antimicrobial agents for application in the ear, ATC code: S02CA04.

Mechanism of action
Triamcinolone acetonide has an anti-inflammatory and vasoconstrictive effect. It suppresses the inflammation reaction and the symptoms of the condition accompanied by itching, but it does not cure the underlying condition. Triamcinolone acetonide is classified as a weak corticosteroid (Class I). The acetic acid in the preparation increases the acidity in the ear, which inhibits the growth of bacteria that can cause an infection.

5.2 Pharmacokinetic properties

When used as prescribed, (virtually) none of the triamcinolone acetonide is absorbed into the systemic circulation.

5.3 Preclinical safety data

No particulars.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetic acid, propylene glycol (E1520), water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months

After opening: use within 4 weeks

6.4 Special precautions for storage

Store in the fridge (2 °C - 8 °C); Do not store in the freezer.
Store in upright position.
For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Triamcinolone acetonide ACE 1 mg/mL, acidic ear drops comes in a brown glass bottle of 10 mL with a clear glass dropper attached to a screw cap and a balloon.
The bottle with the dropper is packaged in a carton with leaflet.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Ace Pharmaceuticals BV
Schepenveld 41
3891 ZK Zeewolde
Netherlands

T: +31 36 547 40 93
E: medinfo@ace-pharm.nl

8. MARKETING AUTHORISATION NUMBER(S)

RVG 126609

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 December 2022

10. DATE OF REVISION OF THE TEXT

Latest partial change concerns section 6.3: 27 March 2023