

1. NAME OF THE MEDICINAL PRODUCT

A-CERUMEN - Ear hygiene solution, in unidose containers.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Gentle surfactants (sodium acyl sarcosinate and sucrose ester), humectant, colouring of vegetable origin, excipients q.s. 100%. Preservative-free colored formula. Colored formula of natural origin
Excipients: For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ear preparation.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

A-CERUMEN is a gentle Ear hygiene solution containing surfactants of natural origin.

A-CERUMEN is recommended for children over 6 months old and adults:

- For regular use, to facilitate the removal of excess wax and prevent blockages.
- To dissolve earwax blockages.

4.2 Posology and method of administration**Posology:**

- For regular ear cleansing: use twice a week.
- For blocked ears: use for 3 to 4 consecutive days, morning and evening.

Method of administration:

- Tilt the head so that the ear to be treated is facing upwards.
- Put half of the contents of a vial into the ear
- Massage the base of the ear.
- Straighten your head in order to let the solution and the earwax residue drag down, then rinse* and wipe the excess.

* Rinse with physiological saline solution or clear water.

4.3 Contraindications

Do not use this product if the eardrum is perforated, you have an ear infection, or if you have myringotomy tubes.

4.4 Special warnings and precautions for use

A-CERUMEN is recommended for children over 6 months old and adults.

Special warnings:

Once opened, a single-dose vial must be used within 24 hours.

Do not refrigerate.

Store between 10-40°C.

Keep away from light

Do not use after the expiry date indicated on the packaging.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Precautions for use:

Do not insert the tip of the vial too far into the ear as this might cause irritation.

Do not use this product if the eardrum is perforated, you have an ear infection, or if you have myringotomy tubes.

If you have ear pain, consult your doctor.

Avoid contact with the eyes.

Do not swallow.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Pregnancy and lactation

No available data.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

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4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotheapeutic group: OTHER OTOLOGICALS,
ATC code: SO2D

5.2 Pharmacokinetic properties

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5.3 Preclinical safety data

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6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capryloyl Glycine, Ethylhexylglycerin, Citric acid, Tetrasodium Glutamate Diacetate, Brown coloring, Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not refrigerate.
Store between 10-40°C.

6.5 Nature and contents of container

Pack of 10x 2 mL doses.

6.6 Special precautions for disposal <and other handling>

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

7. MARKETING AUTHORISATION HOLDER

Laboratoires Gilbert
Avenue du Général de Gaulle,
14200 Herouville Saint-Clair, FRANCE.

8. MARKETING AUTHORISATION NUMBER(S)

< [To be completed nationally]>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

< {DD/MM/YYYY} > < {DD month YYYY} >

< [To be completed nationally] >

10. DATE OF REVISION OF THE TEXT

< {MM/YYYY} >

< [To be completed nationally] >