

**Appendix 5**  
**PATIENT INFORMATION LEAFLET**

**LEAFLET****(A-CERUMEN)****Ear hygiene**

EN

**What does cerumen do?**

Cerumen (earwax) protects ears from infection, dust and foreign bodies. It allows regulation of germs present naturally on the surface of the skin of the external ear canal. It also lubricates the eardrum, which would otherwise become hard, rigid and would no longer transmit sound clearly.

**Why is ear hygiene important?**

Basically, wax works its way out to the outer ear naturally when the jaw makes chewing movements. Dysfunction in this process causes wax build up. The blockage formed stops the ear from functioning properly and may cause hearing loss, ringing or vertigo.

Using a gentle Ear hygiene solution helps to keep the outer ear clean and prevent wax blockages.

**What is A-CERUMEN?**

**A-CERUMEN** is a gentle Ear hygiene solution containing surfactants.

**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.

**How does A-CERUMEN work?**

A-CERUMEN moistens and dissolves wax blockages (dried, impacted wax).

Once the blockage is removed, the wax is naturally secreted again to protect and lubricate the ear.

**Presentation :**

|              |                                                                           |
|--------------|---------------------------------------------------------------------------|
| 40 mL spray. | Pack of X 2 mL doses.<br>Unidose packaging allows ease and safety of use. |
|--------------|---------------------------------------------------------------------------|

**Composition:**

Gentle surfactants (sodium acyl sarcosinate and sucrose ester), humectant, colouring of vegetable origin, recipients q.s. 100%. Preservative-free colored formula. Colored formula of natural origin.

**Dosage:**

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

**Instructions for use:**

1. Tilt the head so that the ear to be treated is facing upwards.
- 2.

| <b>[40 mL spray]</b>      | <b>[2 mL unidose]</b>                            |
|---------------------------|--------------------------------------------------|
| Spray twice into the ear. | Put half of the contents of a vial into the ear. |

3. Massage the base of the ear.

4. 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

**Warnings:**

| [40 mL spray]                                                                                                                                          | [2 mL unidose]                                                                                                                                                                                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Use bottle 3 months after first opening.<br>Do not refrigerate.<br>Store between 10-40°C.<br>Do not use after the expiry date indicated on the bottle. | Once opened, a single-dose vial must be used within 24 hours.<br>Do not refrigerate.<br>Keep away from light<br>Store between 10-40°C.<br>Do not use after the expiry date indicated on the unidose.<br>Do not use a damaged vial. |

**Precautions for use:**

| [40 mL spray]                                                                                                                                                                                                                                                                                                                                                                                                                                                            | [2 mL unidose]                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Do not insert the tip of the spray container too far into the ear as this might cause irritation.<br><br>Do not use this product if the eardrum is perforated, you have an ear infection, or if you have myringotomy tubes.<br><br>If you have ear pain, consult your doctor.<br><br>Avoid contact with the eyes.<br><br>Do not swallow.<br><br>After each use, remove the nozzle and wash it with hot water.<br><br><b>KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.</b> | Do not insert the tip of the vial too far into the ear as this might cause irritation.<br><br>Do not use this product if the eardrum is perforated, you have an ear infection, or if you have myringotomy tubes.<br><br>If you have ear pain, consult your doctor.<br><br>Avoid contact with the eyes.<br><br>Do not swallow.<br><br><b>KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.</b> |



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