# linfoVir oto cerume ear spray

# Medical device

# 45 ml bottle with dispenser

Read these instructions carefully before using the product. Keep this leaflet, as you may need to read it again. Use of this product is strictly personal: LinfoVir® Oto Cerume ear spray should not be shared with other people.

For further information or in case of doubt, consult your doctor or pharmacist.

# WHAT IS IT, AND WHAT IS IT USED FOR

LinfoVir<sup>®</sup> Oto Cerume ear spray has been scientifically developed to remove accumulations of earwax from the external ear canal and/or to prevent excessive earwax build-up. It comes in a 45 ml spray bottle.

Contains hydrogen peroxide, which acts by releasing oxygen that can mechanically break earwax down into smaller fragments that are easier to remove. The product may be useful in preventing the need for ear irrigation.

In addition to hydrogen peroxide, LinfoVir® Oto Cerume ear spray contains a stabiliser that, acting as a buffer, maintains slightly acidic pH values, consistent with the physiology of the external ear canal.

## WHO CAN USE LINFOVIR® OTO CERUME EAR SPRAY

The product is suitable for adults and children starting from 9 years of age.

## DO NOT USE IF:

- You are allergic to hydrogen peroxide;
- You suffer from any form of otitis (e.g. pain, infection, discharge);
- You have, or suspect you may have, a perforated eardrum;
- A tympanostomy drainage tube is present in the ear;
- You have recently undergone ear surgery; unless otherwise indicated by your doctor.

## **USE IN COMBINATION WITH OTHER PRODUCTS/MEDICINES**

LinfoVir® Oto Cerume ear spray does not interfere with other products or medicines that may be used at the same time, however it is recommended to avoid using other otological products with LinfoVir® Oto Cerume ear spray. In case of doubt ask your doctor or pharmacist.

#### HOW TO USE

LinfoVir<sup>®</sup> Oto Cerume ear spray is applied using the dispensing device specifically designed for use in the external ear canal, as shown in the drawings below. Before use, remove any hearing aid that may be present.

For first use, insert the ear spray dispenser onto the bottle by applying a light pressure; spray repeatedly until the liquid starts to come out.



**1** • Tilt your head and point your ear upwards by gently pulling it backwards.



2 • Place the dispensing device into the external ear canal and spray the product. Follow the dosage instructions given in the table below. Keep your head tilted for at least 2 minutes to allow the product to take effect.

**3**•Then turn your head in the opposite direction to allow the release of excess fluid, and gently dry your ear with a clean cloth.





4 Rinse the dispenser with water and dry it carefully. Return the product to its box for future applications.

**IMPORTANT:** Before each use, spray a few times until the liquid comes out, and then follow the instructions (1 to 4).

For proper storage, keep the bottle inside the box.

#### HOW MUCH LINFOVIR® OTO CERUME EAR SPRAY TO USE, AND FOR HOW LONG

Follow the dosing schedule shown in the table below, unless indicated otherwise by your doctor.

The dosages vary depending on whether LinfoVir® Oto Cerume ear spray is used to treat already formed earwax blockages or as a preventive measure.

| AGE                                     | DOSAGE     | EARWAX BLOCKAGE             | PREVENTION   |
|---|------------|-----------------------------|--|
| • Children over 9 years old<br>• Adults | 4-5 sprays | twice a day<br>for 3-5 days | 2 or 3 times a week<br>for ear blockage removal<br>2 or 3 times a year |

# **POSSIBLE SIDE EFFECTS**

Individuals using this product will not necessarily experience the side effects described below or others. It has been reported that otological solutions can occasionally cause discomfort, pain, temporary hearing loss (due to the presence of fluid in the external ear canal), dizziness, skin irritation and, in rare cases, itching. The release of oxygen may cause a temporary bubbling sensation.

If you experience excessive discomfort, pain, loss of hearing or other side effects not mentioned here, stop the treatment and contact your doctor.

#### WARNINGS AND PRECAUTIONS

Consult your doctor if the condition worsens or does not improve within a reasonable period of time.

External use only. Use only in the ear. In case of accidental contact with the eyes, rinse immediately with plenty of water. Do not swallow. In case of accidental ingestion, contact your nearest Poison Control Centre. This product may stain clothes. During pregnancy or breastfeeding, consult your doctor before use. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authorities.

#### **STORAGE CONDITIONS**

Keep out of the reach of children. Store at a temperature not exceeding 30°C. Store in an upright position.

Do not refill the bottle once the drops have been used. Do not freeze. Do not use after the expiry date indicated on the packaging, even if the product is unopened. Use within 12 months after opening.

#### COMPOSITION

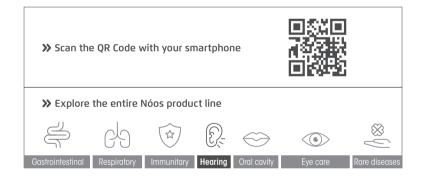
3% hydrogen peroxide; stabiliser.

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Check your local municipal guidelines





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