

Medical device

18 ml bottle with dropper

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 drops 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[®] Oto Cerume ear drops 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 an 18 ml dropper 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 drops 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 DROPS

The product is suitable starting from 3 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

The product 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 drops.

In case of doubt ask your doctor or pharmacist.

HOW TO USE

Before use, remove any hearing aid that may be present. For first use of the product, unscrew the plastic cap until the safety seal is broken.



- Keep your heard tilted to one side so that the ear is facing upwards.
- Gently pull the ear backwards and upwards to straighten the external ear canal and apply the drops. Keep your head tilted for at least 2 minutes to allow the product to take effect.
- Then turn your head in the opposite direction to allow the release of excess fluid and gently dry your ear with a clean cloth.

Close the bottle carefully after use and keep it in its original packaging for proper storage.

HOW MUCH LINFOVIR® OTO CERUME EAR DROPS 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 drop is used to treat already formed earwax blockages or as a preventive measure.

AGE	DOSAGE	EARWAX BLOCKAGE	PREVENTION
Children from 3 to 9 years old	10 drops	twice a day for 3-5 days	2 or 3 times a week for ear blockage removal 2 or 3 times a year
 Children over 9 years old Adults 	16-20 drops		

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

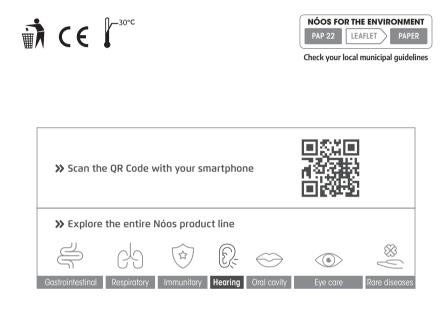
Keep out of the reach of children. Store at a temperature not exceeding 30°C. Store in an upright position.

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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Manufacturer: Mitelos Bioscience S.L., Parc Tecnològic del Vallès, Ronda de Can Fatjó 7-B, 08290 Cerdanyola del Vallès. Barcellona, Spain Product licensed by MITELOS BIOSCIENCE, S.L.



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