

OTIBLOCK[®]

ear spray

INSTRUCTIONS FOR USE

Please, read these instructions for use carefully before you start using this product. Keep them, you may need to read them again. If you require additional information or have any further questions, ask your doctor or pharmacist.

What OTIBLOCK[®] ear spray is and what it is used for:

OTIBLOCK[®] is a cerumenolytic solution scientifically formulated to soften and dissolve earwax from the external ear canal. It can be administered to:

- Remove impacted earwax.
- Prevent excessive accumulation of earwax, as a secondary prevention, to reduce future episodes.
- Ease the irrigation or earwax manual removal procedures, improving the patient tolerability.

The functional ingredient is hydrogen peroxide. This works by releasing oxygen, which breaks up the earwax into smaller fragments that are easier to eliminate.

In addition to hydrogen peroxide, OTIBLOCK[®] contains a buffer that acts as a stabiliser to maintain a slightly acidic pH, consistent with the physiology of the external ear canal.

OTIBLOCK[®] comes in a 45 ml bottle with an ear dispensing device.

Who can use OTIBLOCK[®] ear spray:

OTIBLOCK[®] is suitable for use in adults and children from 3 years.

In the case of children, the product must be administered by a parent, caregiver, or healthcare professional. Children should not self-administer this product.

In individuals with physical or mental impairments, the product should only be used under the supervision of a caregiver or healthcare professional to ensure correct and safe application.

Do not use OTIBLOCK[®] ear spray if:

- you are allergic to any of the ingredients;
- you have, or suspect that you may have, an ear infection (can present with pain, fever, discharge...);
- you have, or suspect that you may have, a perforated eardrum;
- you have tympanostomy (ventilation) tubes; or
- you have had a recent ear surgery unless specifically cleared by the doctor.

Using other products or medicines with OTIBLOCK[®] ear spray:

OTIBLOCK[®] will not interact with any other product or medicine that you may be taking.

However, do not use any other ear product during the course of treatment.

In case of doubt ask your doctor or pharmacist.

How to use OTIBLOCK[®] ear spray:

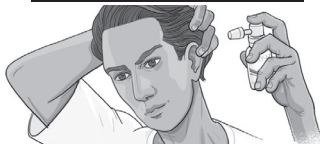
OTIBLOCK[®] dispensing device specially designed for use in the external ear canal as shown in the drawings below.

If you use hearing aids, you must remove them before using OTIBLOCK[®]

Before using OTIBLOCK[®], assemble the ear dispensing device with the bottle by exerting slight pressure.



1. Before each use spray repeatedly out of the external ear canal until the liquid comes out



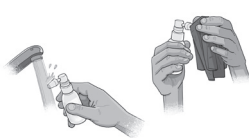
2. Tilt the head so that affected ear faces upward and gently pull the ear backwards.



3. Place the ear dispensing device in the external ear canal, with particular care in children below 9 years, and press it (to know the dosage, see the next section. How often to use OTIBLOCK[®] ear spray). Keep the head tilted for about 2 minutes.



4. Turn the head in the opposite direction to allow the liquid to drain and dry holding a clean tissue.



5. Clean the ear dispensing device with water and dry it. Keep it for future applications.

Keep the bottle inside the carton for proper conservation.

How often to use OTIBLOCK® ear spray:

Follow the recommendations in this table unless your doctor recommends a different schedule.

The schedule of administration varies if OTIBLOCK® ear spray is used to treat an already formed earwax blockage, or if you want to prevent its formation. Children from 3 to 9 years old have a smaller external ear canal and they need a smaller quantity of liquid.

Age	Dosage (n° of puffs)	Recommended treatment regimen	
		Earwax impaction	Prevention of excessive accumulation of earwax
Children from 3 to 9 years old:	press 2 or 3 times	Twice a day for 3 to 5 days	If you need earwax removal procedure twice per year, use OTIBLOCK® twice a week. If you need earwax removal procedure three times per year, use OTIBLOCK® three times per week, and so on.
Adults and children over 9 years old:	press 4 or 5 times		

Do not worry if you use too much OTIBLOCK®. Simply wipe away any surplus running from the ear with a tissue.

Possible side effects:

Just because a side effect is stated here, it does not mean that all people using this product will experience that or any other side effect.

It has been reported that cerumenolytic solutions may cause discomfort, pain, transient hearing loss (due to the liquid presence in the ear canal), dizziness, allergic reactions, potential external otitis, and skin irritation.

On rare occasions, it has been reported that it can cause itching.

The release of oxygen may cause a temporary bubbling sensation.

In case of excessive pain or discomfort or loss of hearing is noticed, as well as any other possible side effects not mentioned before, you should stop using the product and seek medical attention.

Warnings and precautions:

USE IN THE EAR ONLY.

Do not share this product with any other person.

Consult your doctor if the problem worsens or persists.

In case of contact with eyes, rinse immediately with plenty of water.

Do not swallow.

In case of poisoning, contact the National Toxicology Service.

This product may stain clothing.

Do not use if package is damaged.

If you are pregnant or breastfeeding, ask your doctor or pharmacist for advice before using OTIBLOCK®. There is no experience regarding the use of OTIBLOCK® during pregnancy and breastfeeding. Therefore, OTIBLOCK® should not be used if you are pregnant or breastfeeding unless recommended by your doctor.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

How to store OTIBLOCK® ear spray:

Keep out of reach of children.

Store below 30 °C.

Store in an upright position.

Do not refill the container.

Do not freeze.

Do not use after the expiry date printed on the carton and bottle, even if the product has not been used.

Product disposal: Residual solution from expired products or those opened more than 12 months ago may be poured down the sink with plenty of water. The other components must be disposed as household waste, according to national/regional/local regulation.

Composition:

Hydrogen peroxide 3%, phosphate buffer 0.815% (dihydrogen sodium phosphate, hydrogen disodium phosphate), water.

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