

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. Do not share this product with any other person. 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[®] ear spray is a product scientifically formulated to remove impacted earwax from the external ear canal. It also helps to prevent excessive earwax build-up in people at increased risk for earwax impaction (for example, the elderly, people with hearing aids, and those with a history of increased earwax production), reducing the need to visit the healthcare provider and undergo ear irrigation or manual removal. In the event of undergoing such procedures OTIBLOCK[®] can improve the patient tolerability.

The active 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.

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 administer it together with any other ear products.

In case of doubt ask your doctor or pharmacist.

How to use OTIBLOCK[®] ear spray:

OTIBLOCK[®] is applied using an ear 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.

		Recommended treatment regimen	
Age	Dosage (n° of puffs)	Earwax blockage	Prevention of excessive earwax build-up
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.

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.

Pregnant or nursing women, please ask your doctor before use.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority.

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.

Use within 12 months after opening.

Composition:

Hydrogen peroxide 3%; phosphate buffers.

Date of last revision of the instruction for use: January 2023.



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