

Otinova® Ear Spray

Self-care for treatment of otitis externa

(ear canal inflammation, swimmer's ear)



Otitis externa – A common infection

Otitis externa is a common condition that 1 in 10 people will experience in their lifetime. It can be caused by regular contact with water which is why it is sometimes called "swimmer's ear". It can also be caused by headphone use, wearing hearing aids or earplugs.

What is otitis externa?

The skin in the ear canal is thin and delicate. Repeated exposure to water, using in-ear headphones or hearing aids can create a humid environment in the ear and can disrupt natural wax production, This can lead to a break down the ear's natural waxy lining that protects it and this results in skin breakages and dryness that bacteria and fungus can thrive in. A consequence of this may cause inflammation and infection.

Itching and irritation can be a sign of mild inflammation in the ear canal and is usually due to cracked or dry skin. The condition can be more painful if caused by infection (bacteria or fungus). The ear canal may swell and fluid may leak from the ears. This inflammation or infection is located in front of the eardrum.

Why do you get otitis externa?

If the natural environment of the outer ear is disturbed and the skin barrier is damaged, e.g. natural waxiness disappears and fails to protect the ear canal from water and humidity, it gives bacteria or fungi a way to enter the skin and create inflammation and/or infection.

You are at increased risk of getting otitis externa if you:

- Swim, dive and shower regularly
- Clean your ear with cotton swabs
- Have psoriasis or other dermatitis
- Use a hearing aid, headphones or earplugs

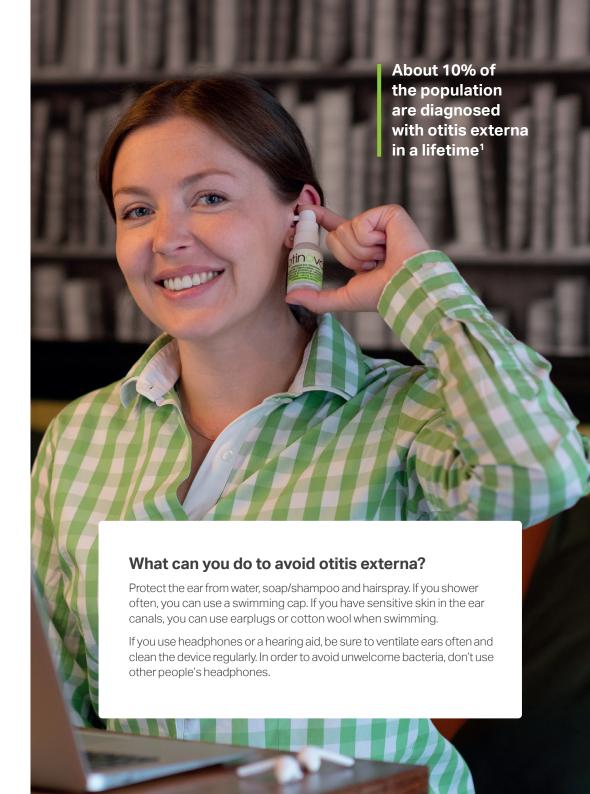












Otinova® Ear Spray – Against otitis externa

Otinova is an easy-to-use antibacterial and anti-fungal ear spray which treats otitis externa. The treatment has a scientifically documented effect on bacterial and fungal attacks.^{2,3,4,5}



Easy to use

The spray function and conical nozzle head make Otinova easy to apply. Spray 1–2 times in the ear canal, morning and evening.



Scientifically and clinically documented effect

The antimicrobial and clinical effects of Otinova are scientifically and clinically documented. $^{2.3,4.5}$



An alternative to antibiotics

Otinova ear spray is a unique self-care medical device for treatment of otitis externa. It is also free of antibiotics.



Content

Otinova contains aluminum acetate, aluminum acetotartrate, acetic acid, water, pH 3–4.

15 ml solution

Each dose of spray contains 0.1 ml and an Otinova bottle contains 150 spray doses.

How does Otinova work?

- Otinova is locally drying, antipruritic and has a bactericidal and fungicidal effect.
- Due to the low pH, Otinova, may help the removal of moisture in the ear canal related to otitis externa or inflammation of the ear canal.
- Otinova has, due to the content of aluminium acetate, an astringent effect on inflamed tissue on the ear canal, thereby increasing the volume of the ear canal.
- Due to the composition, Otinova may provide a soothing effect on itching within the ear canal associated with inflammation/otitis externa.



INTERVIEW

Observations in clinical everyday life

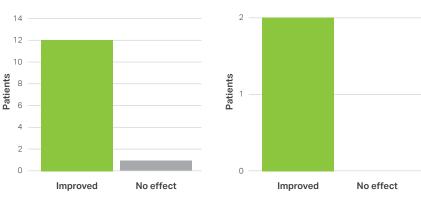
When Mats Engström, associate professor ENT, senior physician, ENT clinic in Läkarhuset, Uppsala, came into contact with Otinova, he collected detailed information about the patients who tried the preparation.

His observations culminated in a report⁶ in which he was able to establish that the results were effective for the indication of otitis externa with or without fungal suspicion.

Otinova showed great effect

on patients with fungal problems

92% of the patients with otitis externa got improved condition



These diagrams are designed for this specific brochure, and are visualisations of the data of the findings in Mats Engströms report. 6

Mats Engström further stated that it can work well to apply Otinova to a tamponade instead of alsol alcohol so that the patient can easily continue with the same preparation after the tamponade has been removed. He also suggested that Otinova may be considered for abundant wax production along with signs of otitis externa, although it should not be considered a first choice.

Side effects were few, but one patient reported burning and another patient experienced discomfort from crystal precipitation in the ear canal.

In his conclusion, Mats Engström wrote that he wants to make his colleagues aware that there is a proven alternative in modern spray packaging for the treatment of otitis externa, and that over-the-counter Otinova is suitable for self-care and prophylactic use when swimming and diving.



Mats Engström, what do you think are the most important experiences to convey regarding your observational study?

- If patients experience discomfort with symptoms related to the ear, such as itching and/or milder pain, it is well worth trying Otinova. The further observations I made after my published report strengthen the conclusion that the preparation works well for the vast majority. It dries out in a good way, and it soothes in a good way.
- I have often advised my patients at the clinic to try Otinova themselves if they have similar problems in the future, as I believe it is a well-functioning self-care product.
- I also think there are strong reasons to try to keep antibiotic use down in general; to simply not use antibiotics unless justified. From that perspective, Otinova is a good alternative for otitis externa, with its antibacterial and antifungal properties.
- There is one aspect that may be good to consider when using Otinova namely the treatment time. It's about the balance between effectiveness and possible unwanted crystal formation, which can cause discomfort and make it difficult to clean the ear canal. The majority of patients with mild otitis externa get better within a few days with Otinova, and treatment up to one week is, in my experience, quite sufficient for the vast majority.



Mats Engström, associate professor ENT, senior physician, ENT clinic in Läkarhuset

Stories from real life

The cases below are collected from two different opencare ENT clinics in Sweden.



The patient

A man in his 60's who had severe problems with fungus in the ear canal for many years. He was earlier treated with Locacorten-Vioform (flumetason-pivalat, kliokinol).

The treatment

The doctor recommended a treatment with Otinova for 7 days, as well as maintenance treatment 1 spray/week continuously.

After 7 days of treatment and subsequent maintenance treatment, the patient was symptom-free.



The patient

An eight year old boy with established otitis externa. He had been treated in two rounds with Terracortril (hydrokortison, oxitetracyklin), without getting a succesful result.

The treatment

His ear was completely blocked. After cleaning a tamponade with Otinova was inserted. The patient hydrated the tamponade for 24 hours, after which the tamponade was removed.

The patient were treated with Otinova 2 sprays 2 times/day for 7 days.

The patient were symptom-free on return visit after 8 days.



Questions and answers

What is Otinova used for?

To treat ear canal inflammation (otitis externa), also called swimmer's ear.

Who should use Otinova?

- People with a tendency to suffer from otitis externa
- Swimmers, divers
- · Users of hearing aids, headphones, earplugs, etc.

Can children use Otinova?

Otinova should not be used by children under 5 years of age without a doctor's recommendation (they should get an eardrum check).

Can pregnant and lactating women use Otinova?

No specific studies in pregnant or lactating women have been conducted, and therefore Otinova should be used with caution. To be absolutely certain you should avoid using Otinova during pregnancy and when breast-feeding.

What does Otinova contain?

Otinova contains aluminum acetate, aluminum acetotartrate, acetic acid, water, pH 3-4.

How does Otinova work?

Otinova has a local astringent, dehydrating, decongestant, antipruritic effect and also has a bactericidal and antifungal effect.

How is Otinova dosed?

Otinova is sprayed 1–2 times in the ear canal morning and evening. The head should then be tilted after spraying so that the liquid reaches the deepest part of the ear canal.

How long can Otinova be used for?

Otinova can be used "intermittently" i.e. during periods of increased risk of developing ear canal inflammation, such as swimming/aquatic sports holidays.

Do not use Otinova for a continuous period of more than 7 days. Salt precipitation in, and severe dehydration of, the ear canal may occur with overdosing and/or long-term use.

How long does a bottle of Otinova last?

Each dose of spray contains 0.1 ml and an Otinova® bottle contains 150 spray doses.

Shelf-life: 6 months after opening. Unopened bottle 3 years from manufacturing date. Store in room temperature.

Why does Otinova sometimes cause a stinging sensation?

Otinova is an acidic solution (pH 3-4 -low pH) and can therefore sting if the ear canal is inflamed and/or sore. The pain usually disappears relatively quickly. If you experience persistent pain, you should contact your doctor.

Why does Otinova smell?

Otinova contains acetic acid, which has a characteristic odour. The smell usually disappears quickly after use.

Can Otinova cause any side effects?

Otinova may cause a slight temporary irritation or a burning sensation in the ear canal. Salt precipitation in, and dehydration of, the ear canal may occur with overdosing and/or long term use.

Isolated cases of eardrum perforation have been reported in association with heavy saline precipitation at high doses for more than 20 days without interruption.

Do not use Otinova if you have known allergies to any of the contents of the product.





For more information visit otinova.com

References

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- **6.** Engström M. et al, Experiences OF Burow's Solution In spray form for otitis externa, Swedish ENT journal, 2014; 3:19. **7.** Rosenfeld et al. Clinical Practice Guideline US: Acute Otitis Externa. American Academy of Otolaryngology Head and Neck Surgery Foundation 2014, vol.150 (IS) S1-S24.

