otinova®

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

About 10% of the population are diagnosed with otitis externa in a lifetime[1]

What can you do to avoid otitis externa?

Protect the ear from water, soap/shampoo and hairspray. If you shower often, you can use a swimming cap. If you have sensitive skin in the ear canals, you can use earplugs or cotton wool when swimming.

If you use headphones or a hearing aid, be sure to ventilate ears often and clean the device regularly. In order to avoid unwelcome bacteria, don't use other people's headphones.

Otinova® Ear Spray – Against otitis externa

Otinova is an easy-to-use antibacterial and anti-fungal ear spray which treats otitis externa.

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

Otinova consists of aluminum acetate, aluminium acetotartrate and acetic acid. The antimicrobial and clinical effects 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 and has a bactericidal and fungicidal effect.
- Due to the composition, Otinova may provide a soothing effect on itching within the ear canal associated with inflammation/otitis externa.
- Otinova may help reduce moisture related to otitis externa or inflammation in the ear canal.
- Otinova has, due to the content of aluminium acetate, an astringent effect on inflamed tissue on the ear canal, thereby reducing swelling of the ear canal.

Otinova has an **anatomically designed nozzle** to help facilitate correct application and dosage

Otinova is designed to be administered in **the form of spray** instead of drops, helping to make it easier to use

Antibiotic-resistant bacteria and fungi

Today, antibiotic resistance is a growing problem in society. Microbiologists believe that antibiotics should be avoided in the treatment of external otitis.

Several clinical studies show that aluminum acetate solution is a safe and effective treatment[2,3] of external otitis and has been found to be at least as effective as medicines containing antibiotics and steroids.[5,6]

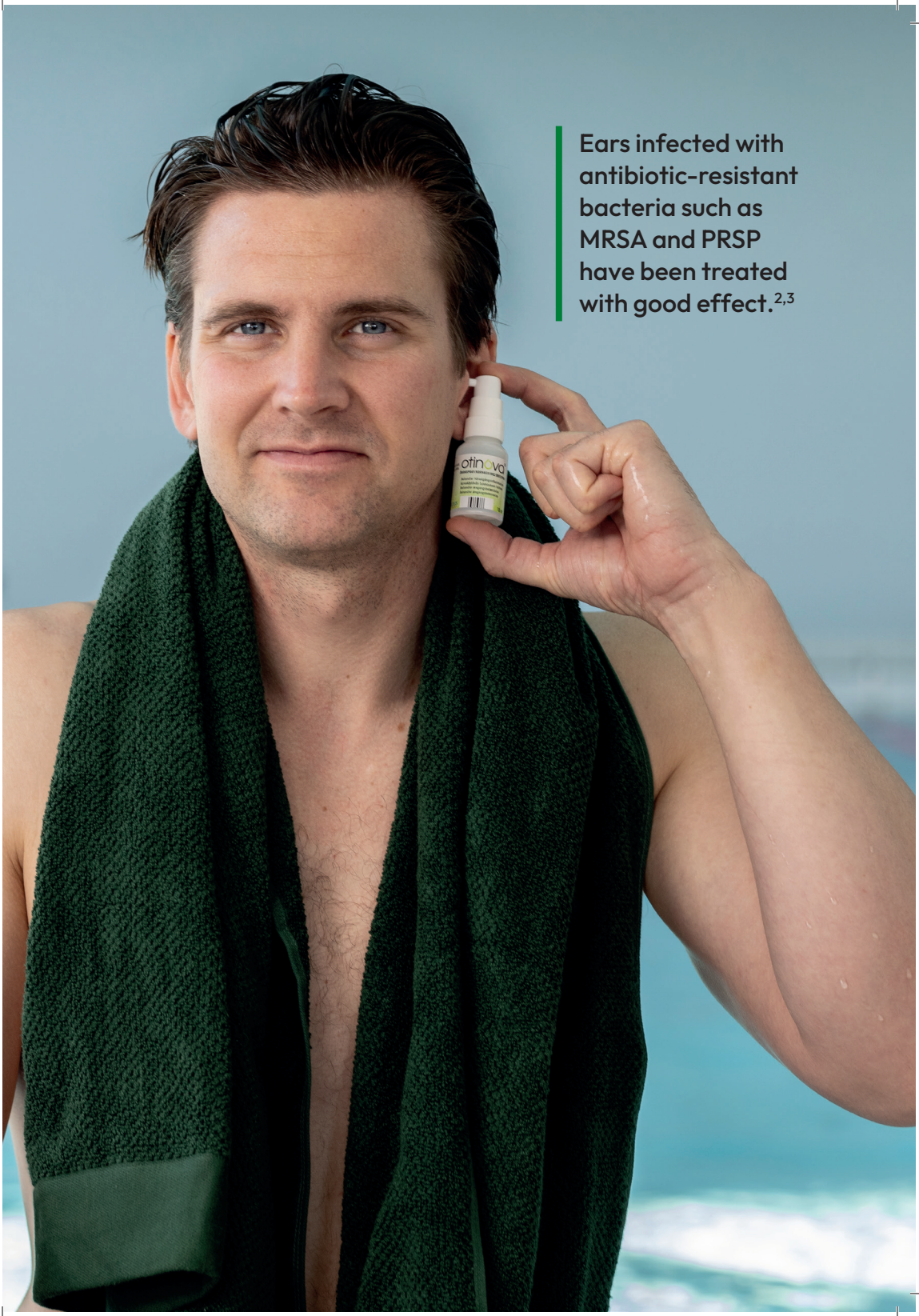
Broad antimicrobial effect has been shown in several studies[2,3,4], which can be explained by a combination of the solution's low pH and content of aluminum acetate. Ears infected with antibiotic-resistant bacteria such as MRSA and PRSP have been treated with good effect.[2,3]

Clinical efficacy has been demonstrated in patients with external otitis / refractory otorrhea / chronic ear disease.[2,3,5,6] The effect is seen on both bacteria and fungi.[2,3]

Effectiveness of aluminum acetate solution on microorganisms identified[3]

Microorganism	No. of cases	Cured	Improved	No change
Fungi	12	12	0	0
- *Aspergillus*	6	6	0	0
- *Candida albicans*	3	3	0	0
- Others	3	3	0	0
Bacteria	37	25	9	3
- MRSA	14	10	3	1
- *S. epidermidis*	5	3	2	0
- *P. aeruginosa*	4	3	1	0
- Others	14	9	3	2
Total	**49**	**37**	**9**	**3**

MRSA, methicillin-resistant Staphylococcus aureus; S. epidermidis, Staphylococcus epidermidis; P. aeruginosa, Pseudomonas aeruginosa.



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The diagnosis of otitis externa is one of the most frequent infections in primary care[7]

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 report[8] in which he was able to establish that the results were effective for the indication of otitis externa with or without fungal suspicion.

Side effects were few, but one patient reported a burning sensation 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. ■

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 who experience mild otitis externa, with symptoms such as itching, discomfort or milder pain.

- Users of hearing aids, headphones, earplugs etc
- Swimmers and divers often experience these symptoms.

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).

What does Otinova contain?

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

How does Otinova work?

Otinova acts locally astringent, reduce swelling and moisture, relieves itching and also has an antibacterial 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.

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For more information
visit otinova.com

References

1. Raza SA, Denholm SW, Wong JC. An audit of the management of otitis externa in an ENT casualty clinic. J Laryngol Otol. 1995;109:130–133. 2. Jinnouchi O et al. Antimicrobial and therapeutic effects of modified Burow's solution on refractory otorrhea. Auris Nasus Larynx. 2012;39:374-377. 3. Kashiwamura M et al. The efficacy of Burow's solution as an ear preparation for the treatment of chronic ear infections. Otol Neurotol. 2004;25:9-13. 4. Hyo Y et al. Antimicrobial effects of Burow's solution on Staphylococcus aureus and Pseudomonas aeruginosa. Med Mol Morphol. 2012;45:66-71. 5. Lambert IJ et al. A comparison of the treatment of otitis externa with "Otosporin" and aluminium acetate: a report from a services practice in Cyprus. J Royal Coll General Pract 1981; 31: 291-294. 7. Clayton et al., Clin Otolaryngol Allied Sci 1990, 15, 7-10. 6. 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 8. Engström M. et al, Experiences OF Burow's Solution In spray form for otitis externa, Swedish ENT journal, 2014; 3:19.

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CIRCIUS PHARMA

Circius Pharma AB | Södra Långebergsgatan 34-36 SE-436 32, Askim, Sweden
Phone: +46 (0)31 81 84 00 | info@circiuspharma.com | circiuspharma.com