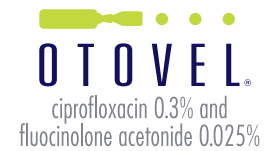


FREQUENTLY ASKED QUESTIONS



What are the benefits of ear tubes if my child gets ear infections anyway?

Tympanostomy tubes may help reduce the incidence, symptoms, and duration of ear infections in children who are prone to acute otitis media (AOM). While ear tubes do not prevent infections, they may provide some benefits^{1,2}:

- Children are far less symptomatic (fever is rare; ear pain is mild or nonexistent)
- The tubes help drain the discharge (otorrhea) so it doesn't build up behind the eardrum
- Less inflammation causes less swelling and results in less ear pain
- Appetite and sleep are rarely interrupted
- Hearing loss due to fluid buildup is prevented
- Avoids spread of AOM infection into to other areas of the head, which could cause potentially life-threatening complications
- Ear infections don't last as long
- Multiple courses of antibiotics are not usually necessary and oral antibiotics can be avoided

How is acute otitis media different in children with ear tubes?

Children with ear tubes usually don't have pain or fever. They are also less likely to have hearing loss. Often the only way to know a child with ear tubes has AOMT is by the sudden appearance of drainage from the ear (otorrhea). This drainage can be thin and milky, thick and smelly, or sticky and mucus-like.¹

How do I know if it's AOMT?

It's likely easy: if there is otorrhea (drainage or discharge), then your child may have AOMT. If not, then it's not likely AOMT. It's always best to see your doctor to get a professional diagnosis.¹

What is antibiotic resistance?

Antibiotic resistance is one of the most important concerns in the medical community today. Antibiotic resistance means that an antibiotic that used to work on a certain bacteria is no longer effective. All 5 of the bacteria (*P. aeruginosa*, *S. pneumoniae*, *S. aureus*, nontypeable *H. influenzae*, and *M. catarrhalis*) that commonly cause ear infections have a propensity to develop resistance to oral antibiotics, although topical antibiotics are typically not associated with the development of resistance.¹

How long does AOMT treatment last?

OTOVEL is used twice a day for 7 days. You should follow your doctor's instructions.³

Why do I have to warm the OTOVEL vial in my hands before I give it to my child?

The ear does more than hear...it also is part of the body's balance system. Putting cold liquid into the ear can cause dizziness because the sudden temperature change stimulates and disrupts the nerves in the middle ear responsible for balance.⁴

What if my child misses a dose of OTOVEL?

If a dose is missed and it is close to the time the dose should have been given, you can give your child the dose. If the dose is missed and it's closer to the time that the next dose should be given, give the next dose at the regular time and keep to the dosing schedule your doctor has prescribed until the medication is gone.

Can I save on my OTOVEL prescription?

Yes, eligible patients can save on OTOVEL® (ciprofloxacin and fluocinolone acetonide). We are committed to making OTOVEL accessible to people who need it. See our savings program for more details.

IMPORTANT SAFETY INFORMATION

INDICATIONS

OTOVEL® (ciprofloxacin and fluocinolone acetonide) is used in children 6 months of age and older, who have a tiny cylinder tube in their eardrum known as a tympanostomy tube to prevent excess fluid in the middle ear. OTOVEL is used to treat a type of middle ear infection called acute otitis media with tympanostomy tubes (AOMT) caused by certain bacteria.

IMPORTANT SAFETY INFORMATION

Do not use OTOVEL if your child:

- Is allergic to quinolones including ciprofloxacin, corticosteroids including fluocinolone acetonide, or any of the ingredients in OTOVEL.
- Has an outer ear canal infection caused by certain viruses including chicken pox (varicella) and the herpes simplex virus, or has a fungal ear infection.

Before using OTOVEL, tell your healthcare provider about all of your child's medical conditions, including if they:

- Are pregnant or plan to become pregnant, although OTOVEL is not expected to harm the baby.
- Are breastfeeding or plan to breastfeed, although OTOVEL is not expected to pass into the breast milk to harm the baby.

Tell your healthcare provider about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Use OTOVEL exactly as your healthcare provider tells you. OTOVEL is for use in the ear only. Do not inject OTOVEL or use OTOVEL in the eye. If symptoms do not improve after 7 days of treatment with OTOVEL, contact your healthcare provider. Do not use OTOVEL for a condition for which it was not prescribed. Do not give OTOVEL to other people, even if they have the same symptoms. It may harm them.

Call your healthcare provider right away if:

- Fluid continues to drain from the ear after finishing treatment with OTOVEL,
- Fluid drains from the ear 2 or more times within 6 months after treatment has stopped.

OTOVEL may cause serious side effects, including allergic reactions. Stop using OTOVEL and contact your healthcare provider if any of the following signs or symptoms of an allergic reaction occur: hives, swelling of your face, lips, mouth, or tongue, rash, itching, trouble breathing, dizziness, fast heartbeat, or pounding in your chest.

The most common side effects of OTOVEL include fluid draining from the ear, ear infection, ear itching, extra tissue that grows on a part of your body that has been injured, swelling of the outer part of the ear, ear pain, or balance problems.

Tell your healthcare provider of any side effects that are bothersome or that do not go away. These are not all the possible side effects of OTOVEL. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information, ask your healthcare provider or pharmacist, or consult the full Prescribing Information located at www.otovel.com



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