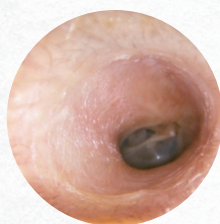


# EAR ANATOMY

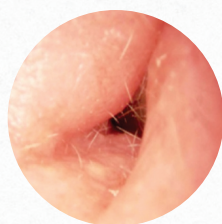
The ear consists of three sections: the outer ear, middle ear, and inner ear. The auricle of the outer ear catches sound waves and directs them into the ear canal. At the end of the ear canal, the sound waves strike the tympanic membrane (the eardrum), causing it to vibrate. On the other side of the eardrum is the middle ear, an air-filled cavity containing three small bones (the ossicles), which transfer the eardrum's vibrations to the inner ear, which is responsible for hearing and balance.

## ➔ ACUTE OTITIS EXTERNA (AOE)

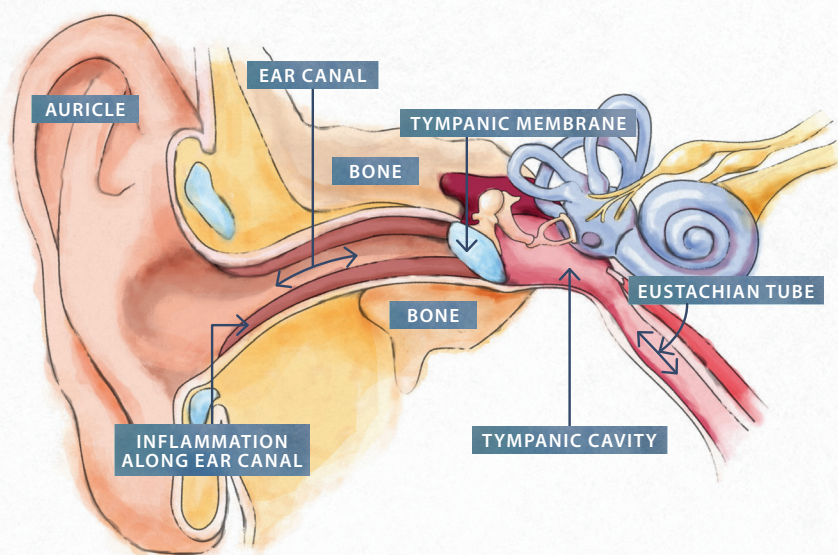
Commonly known as "Swimmer's Ear," Acute Otitis Externa is an inflammation of the external ear canal commonly caused by bacterial infections<sup>1</sup>.



Healthy external canal



Swollen external canal



## IMPORTANT SAFETY INFORMATION AND INSTRUCTIONS

### What is CIPRODEX® Otic?

CIPRODEX® Otic is an antibiotic/steroid combination product in a sterile suspension used to treat:

**Outer Ear Canal Infection in Patients 6 Months and Older:** An outer ear canal infection, also known as "Swimmer's Ear," is a bacterial infection of the outer ear canal. The ear canal and the outer part of the ear may swell, turn red, and be painful. Also, a fluid discharge may appear in the ear canal.

### Who should NOT use CIPRODEX® Otic?

- Do not use this product if allergic to ciprofloxacin or to other quinolone antibiotics.
- Do not use this product if allergic to dexamethasone or to other steroids.
- Do not give this product to pediatric patients who are less than 6 months old.

### How often should CIPRODEX® Otic be given?

CIPRODEX® Otic ear drops should be given 2 times each day (about 12 hours apart, for example, 8 AM and 8 PM) in each infected ear unless the doctor has instructed otherwise. The best times to use the ear drops are in the morning and at night. It is very important to use the ear drops for as long as the doctor has instructed, **even if the symptoms improve**. If CIPRODEX® Otic ear drops are not used for as long as the doctor has instructed, the infection may return.

### What if a dose is missed?

If a dose of CIPRODEX® Otic is missed, it should be given as soon as possible. If it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not use a double dose unless the doctor has instructed you to do so. If the infection is not improved after one week, you should consult

your doctor. If you have two or more episodes of drainage within six months, it is recommended you see your doctor for further evaluation.

### What activities should be avoided while using CIPRODEX® Otic?

It is important that the infected ear(s) remain clean and dry. When bathing, avoid getting the infected ear(s) wet. Avoid swimming unless the doctor has instructed otherwise.

### What are the possible side effects of CIPRODEX® Otic?

During the testing of CIPRODEX® Otic for ear canal infections, the most common side effect related to CIPRODEX® Otic was itching of the ear that occurred in 1 to 2 out of 100 patients. Other common side effects were: ear debris; ear infection in the treated ear; ear congestion; ear pain; and rash. If any of these side effects persist, call the doctor. If an allergic reaction to CIPRODEX® Otic occurs, stop using the product and contact your doctor.

### DO NOT TAKE BY MOUTH

If CIPRODEX® Otic is accidentally swallowed or overdose occurs, call the doctor immediately. This medicine is available only with a doctor's prescription. Use only as directed. Do not use this medicine if outdated. If you wish to learn more about CIPRODEX® Otic, call your doctor or pharmacist.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

**For additional information about CIPRODEX® Otic, please refer to the accompanying full prescribing information.**

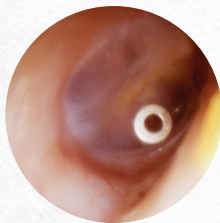


# EAR ANATOMY

The ear consists of three sections: the outer ear, middle ear, and inner ear. The auricle of the outer ear catches sound waves and directs them into the ear canal. At the end of the ear canal, the sound waves strike the tympanic membrane (the eardrum), causing it to vibrate. On the other side of the eardrum is the middle ear, an air-filled cavity containing three small bones (the ossicles), which transfer the eardrum's vibrations to the inner ear, which is responsible for hearing and balance.

## ➔ ACUTE OTITIS MEDIA WITH TYMPANOSTOMY TUBES (AOMT)

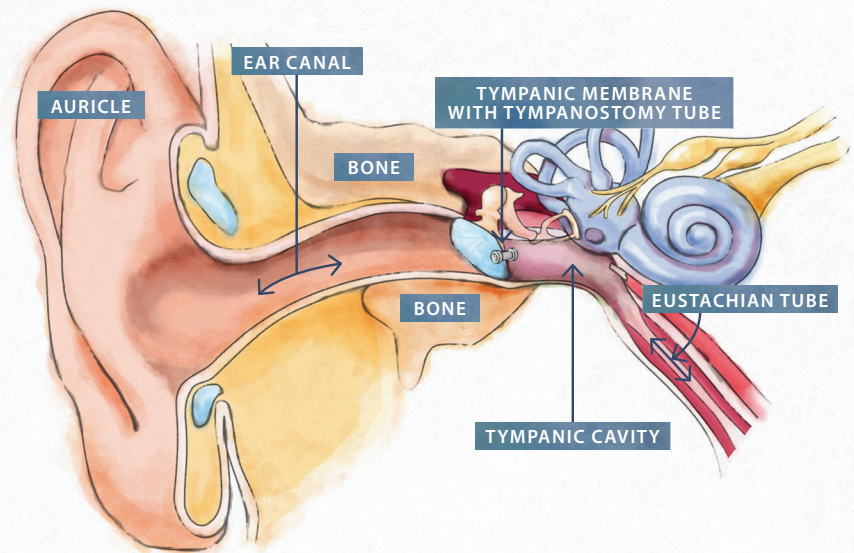
Acute Otitis Media with Tympanostomy Tubes is an infection that occurs behind the eardrum in the middle ear when a tympanostomy tube is in place<sup>2</sup>.



A healthy ear with a tympanostomy tube



Visible otorrhea in a patient with AOM with tympanostomy tube



### IMPORTANT SAFETY INFORMATION AND INSTRUCTIONS

#### What is CIPRODEX® Otic?

CIPRODEX® Otic is an antibiotic/steroid combination product in a sterile suspension used to treat:

**Middle Ear Infection with Drainage through a Tube in Children 6 Months and Older:** A middle ear infection is a bacterial infection behind the eardrum. People with a tube in the eardrum may notice drainage from the ear canal.

#### Who should NOT use CIPRODEX® Otic?

- Do not use this product if allergic to ciprofloxacin or to other quinolone antibiotics.
- Do not use this product if allergic to dexamethasone or to other steroids.
- Do not give this product to pediatric patients who are less than 6 months old.

#### How often should CIPRODEX® Otic be given?

CIPRODEX® Otic ear drops should be given 2 times each day (about 12 hours apart, for example, 8 AM and 8 PM) in each infected ear unless the doctor has instructed otherwise. The best times to use the ear drops are in the morning and at night. It is very important to use the ear drops for as long as the doctor has instructed, **even if the symptoms improve**. If CIPRODEX® Otic ear drops are not used for as long as the doctor has instructed, the infection may return.

#### What if a dose is missed?

If a dose of CIPRODEX® Otic is missed, it should be given as soon as possible. If it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not use a double dose unless the doctor has instructed you to do so. If the infection is not improved after one week, you should consult your doctor. If you have two or more episodes of drainage within six months, it is recommended you see your doctor for further evaluation.

#### What activities should be avoided while using CIPRODEX® Otic?

It is important that the infected ear(s) remain clean and dry. When bathing, avoid getting the infected ear(s) wet. Avoid swimming unless the doctor has instructed otherwise.

#### What are the possible side effects of CIPRODEX® Otic?

During the testing of CIPRODEX® Otic for middle ear infections, the most common side effect related to CIPRODEX® Otic was ear discomfort that occurred in up to 3 out of 100 patients. Other common side effects were: ear pain; ear precipitate (residue); irritability; and abnormal taste. If any of these side effects persist, call the doctor. If an allergic reaction to CIPRODEX® Otic occurs, stop using the product and contact your doctor.

#### DO NOT TAKE BY MOUTH

If CIPRODEX® Otic is accidentally swallowed or overdose occurs, call the doctor immediately. This medicine is available only with a doctor's prescription. Use only as directed. Do not use this medicine if outdated. If you wish to learn more about CIPRODEX® Otic, call your doctor or pharmacist.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

**For additional information about CIPRODEX® Otic, please refer to the accompanying full prescribing information.**

**References:** 1. Rosenfeld RM, Schwartz SR, Cannon CR, et al. Clinical practice guideline: acute otitis externa. *Otolaryngol Head Neck Surg.* February 2014 vol. 150 no. 1 suppl S1-S24. 2. Rosenfeld RM, Schwartz SR, Pynnonen MA, et al. Clinical practice guideline: tympanostomy tubes in children. *Otolaryngol Head Neck Surg.* 2013;139(1 suppl):S1-S35.