BE THE HEARO

Offer your patients single-dose treatment for AOE and bilateral OME/TTP.

AOE, acute otitis externa; OME/TTP, otitis media with effusion undergoing tympanostomy tube placement.

INDICATIONS AND USAGE

OTIPRIO (ciprofloxacin otic suspension) 6% is a fluoroquinolone antibacterial indicated for:

- The treatment of acute otitis externa in patients 6 months of age and older due to *Pseudomonas aeruginosa* and *Staphylococcus aureus*
- The treatment of pediatric patients (6 months of age and older) with bilateral otitis media with effusion undergoing tympanostomy tube placement

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

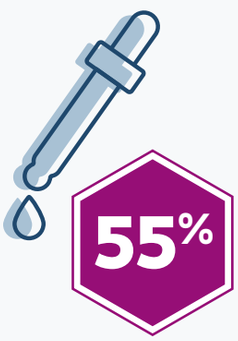
OTIPRIO (ciprofloxacin otic suspension) 6% is contraindicated in patients with a history of hypersensitivity to ciprofloxacin, to other quinolones, or to any of the components of OTIPRIO.

Please see Important Safety Information throughout and click here for full Prescribing Information.

OTIPRIO®
ciprofloxacin otic suspension 6%

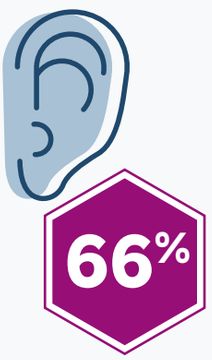
In the hands of caregivers and patients, otic-drop regimens may lead to inadequate treatment

In a caregiver survey (N=71) among those responsible for giving otic drops to children[1]:



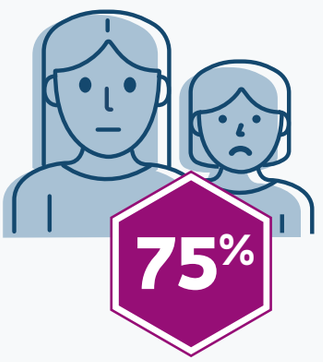
55%

of caregivers **missed or forgot to administer** otic drops



66%

of caregivers were **not "very confident"** that the correct amount entered the ear



75%

of caregivers reported their child was **upset when drops were administered**

In a separate study (N=39) of the accuracy of patient self-medication with otic drops, compliance patterns were extremely poor; only 40% of patients managed to self-medicate within a 25% error margin by the end of day 3.[2]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Potential for Microbial Overgrowth: OTIPRIO may result in overgrowth of non-susceptible bacteria and fungi. If such infections occur, institute alternative therapy.

Please see Important Safety Information throughout and click here for full Prescribing Information.

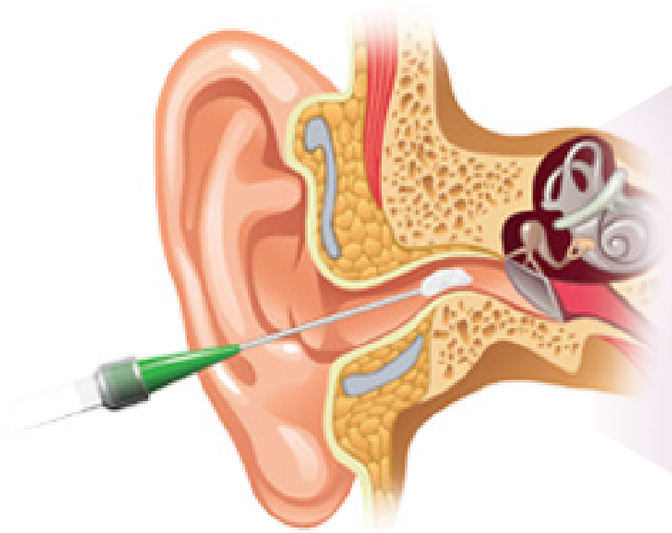
OTIPRIO®
ciprofloxacin otic suspension 6%

OTIPRIO® keeps treatment in your hands

The first and only ciprofloxacin otic suspension administered in a single dose by a healthcare professional

- Delivers the full treatment of ciprofloxacin in your office or clinic
- Assures that treatment isn't compromised by inadequate drug delivery or noncompliance
- Eliminates the hassles and uncertainty of drops administered by caregivers and patients at home

OTIPRIO uses proprietary technology to ensure that delivery of otic antibiotic treatment is complete and consistent



Thermosensitive technology transitions OTIPRIO from a liquid to a gel in the ear, allowing delivery of a full treatment with a single dose.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

Acute otitis externa clinical trial: Adverse reactions (incidence at least 2%) with OTIPRIO vs sham were: ear pruritus (2% vs 2%), headache (2% vs 1%), otitis media (2% vs 1%), and ear discomfort (2% vs 0%).

Bilateral otitis media with effusion clinical trials: Adverse reactions (incidence at least 3%) with OTIPRIO vs sham were: nasopharyngitis (5% vs 4%), irritability (5% vs 3%), and rhinorrhea (3% vs 2%).

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OTIPRIO®
ciprofloxacin otic suspension 6%

Drop administration may be a challenge for many patients with AOE

Not actual patient.

LUKE
AGE 7

- Fussy and uncooperative
- Multiple caregivers over different days
- Receives several medications daily

AOE, acute otitis externa.

IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

Pediatric Use: The safety and effectiveness of OTIPRIO in infants below six months of age have not been established for the treatment of pediatric patients with acute otitis externa and bilateral otitis media with effusion undergoing tympanostomy tube placement.

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OTIPRIO®
ciprofloxacin otic suspension 6%

Drop administration may be a challenge for many patients with AOE

CARRIE
AGE 19

- Unresolved AOE after 3 weeks
- Studying for college exams
- Frequent travel for swim meets
- Suspected noncompliance with otic drops

Not actual patient.

Not actual patient.

HAL
AGE 70

- Osteoarthritis
- Lives alone
- Poor dexterity

AOE, acute otitis externa.

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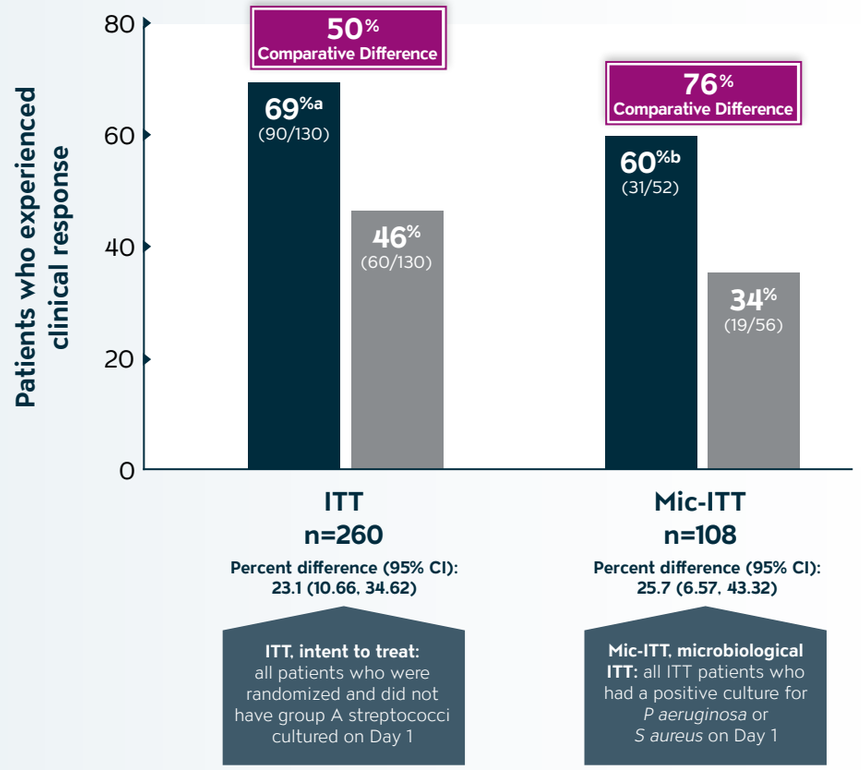
OTIPRIO®
ciprofloxacin otic suspension 6%

In the treatment of AOE in patients 6 months of age and older due to *Pseudomonas aeruginosa* and *Staphylococcus aureus*

Proven efficacy with a single in-office dose in pediatric and adult patients with AOE

Significantly more patients given OTIPRIO® vs a sham treatment achieved the primary end point of clinical response at Day 8[3]

Proportion of patients with clinical response at study Day 8



Study design: Phase 3, randomized, controlled, blinded, multicenter study in 262 pediatric and adult patients with unilateral or bilateral acute otitis externa.[3]

Clinical response was defined as the complete absence of signs and symptoms of acute otitis externa (ie, tenderness, erythema, edema, and otorrhea, as determined by the blinded investigator), and no concomitant systemic or topical antibacterial drug (given in the study ear) was taken for any reason at or prior to the study visit.[3]

Proven efficacy against both *P aeruginosa* and *S aureus*, the 2 most common isolates in AOE[4]

[a]*P*<0.001 from a Fisher's exact test.[3]

[b]*P*=0.012 from a Fisher's exact test.[3]

AOE, acute otitis externa.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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In the treatment of AOE in patients 6 months of age and older due to *Pseudomonas aeruginosa* and *Staphylococcus aureus*

Proven efficacy with a single in-office dose in pediatric and adult patients with AOE

Cumulative proportion of subjects with cessation of otorrhea (secondary end point)[5]

Rates of otorrhea cessation for patients who received **OTIPRIO®** (n=130) vs **sham** (n=130), respectively, were

Day 8[a]	**72.4%** vs **47.4%**
Day 15[a]	**72.4%** vs **43.2%**
Day 29[a]	**73.6%** vs **35.8%**

[a]*P*<0.001 at each time point. Rates of otorrhea cessation are based on nn, the number of subjects in the ITT population with otorrhea (nn=87 and nn=95 for OTIPRIO and sham, respectively).

Well tolerated in the phase 3 clinical trial in patients with AOE

The incidence of adverse reactions was similar in both treatment arms[3]

Adverse reactions that occurred in at least 2% of OTIPRIO patients and at an incidence greater than sham	**OTIPRIO** (n=127)	**Sham** (n=132)
Ear pruritus	**2%**	**2%**
Headache	**2%**	**1%**
Otitis media	**2%**	**1%**
Ear discomfort	**2%**	**0%**

AOE, acute otitis externa.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Potential for Microbial Overgrowth: OTIPRIO may result in overgrowth of non-susceptible bacteria and fungi. If such infections occur, institute alternative therapy.

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OTIPRIO®
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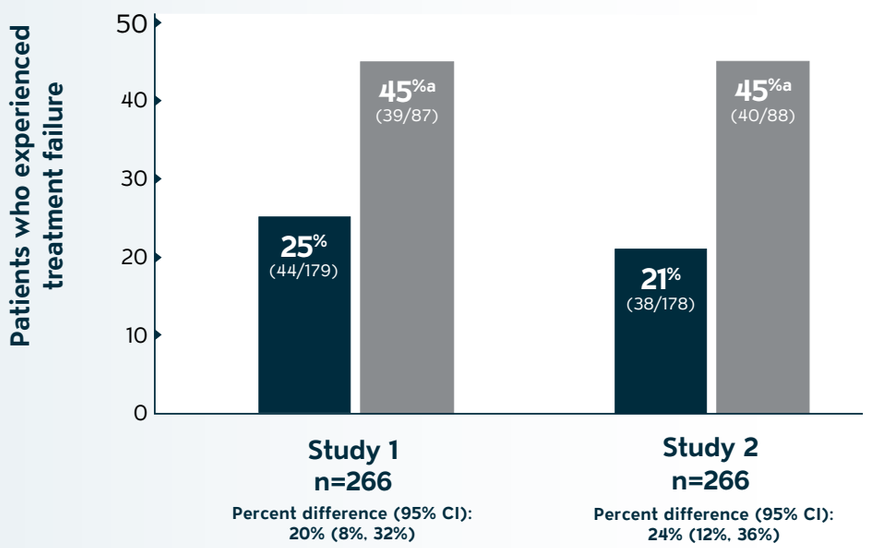
In pediatric patients 6 months of age and older with bilateral OME undergoing TTP

Proven efficacy with a single intra-operative dose

OTIPRIO® demonstrated statistically significant lower rates of treatment failure than tubes alone[3]

Primary end point—Day 15 treatment failure rates (intent-to-treat population: included all randomized patients)



OTIPRIO + Tubes
Sham
[a]*P*<0.001

Study design: 2 randomized, multicenter, sham-controlled clinical trials compared the efficacy and safety of OTIPRIO with tubes vs tubes alone in pediatric patients (N=532) aged ≥6 months with bilateral middle-ear effusion requiring ear tube placement.[3]

Treatment failure was defined as occurrence of any of the following events: otorrhea as determined by a blinded assessor on or after 3 days postsurgery; otic or systemic antibacterial drug use for any reason any time postsurgery; or patients who missed visits or were lost to follow-up.[3]

Administration of OTIPRIO did not lead to impairment in hearing function, middle-ear function, or tube patency by Day 29.[3]

OTIPRIO reduced treatment failure across effusion types[7]

Cumulative proportion of treatment failures through Day 15 by baseline[b] effusion type[c] (in at least 1 ear)[d]

	Serous (n=212)	Purulent (n=70)	Sanguineous (n=5)	Mucoid (n=305)
Tubes alone	**43.3%** (29/67)	**71.4%** (15/21)	**25%** (1/4)	**43.7%** (45/103)
OTIPRIO	**20.7%** (30/145)	**28.6%** (14/49)	**0%** (0/1)	**23.3%** (47/202)
Comparative difference	**52.2%**	**60.0%**	**N/A**	**47.0%**

[b]Baseline was defined as the last measurement taken on or prior to the day of randomization.[7]
[c]Effusion type was unknown and not recorded for 6 patients.[3] Sanguineous effusion had too few events to reach any meaningful conclusion.[7]
[d]Subpopulation analysis of the primary end point.[7]

OME, otitis media with effusion; TTP, tympanostomy tube placement.

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In pediatric patients 6 months of age and older with bilateral OME undergoing TTP

Well tolerated in phase 3 clinical trials

The incidence of adverse reactions was similar in both treatment arms[3]

Adverse reactions that occurred in at least 3% of patients treated with OTIPRIO® and at an incidence greater than patients treated with tubes alone	OTIPRIO (n=357)	Tubes alone[a] (n=173)
Nasopharyngitis	5%	4%
Irritability	5%	3%
Rhinorrhea	3%	2%

[a]Tubes-alone arm: patients received an administration of air (sham) during ear tube placement.[6]

OME, otitis media with effusion; TTP, tympanostomy tube placement.

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ADVERSE REACTIONS

Bilateral otitis media with effusion clinical trials: Adverse reactions (incidence at least 3%) with OTIPRIO vs sham were: nasopharyngitis (5% vs 4%), irritability (5% vs 3%), and rhinorrhea (3% vs 2%).

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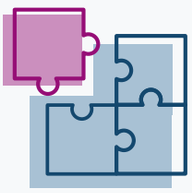
OTIPRIO®: More control is in your hands

Delivers a full treatment in a single dose administered by an HCP in the office or clinic

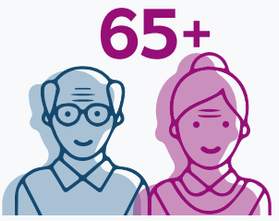
- Assures treatment isn't compromised by inadequate drug delivery
- Removes the burden and responsibility of otic-drop administration from caregivers and patients
- Well tolerated in patients with AOE
- In AOE, significantly more patients given OTIPRIO vs a sham treatment achieved the primary end point of clinical response at Day 8[3]

Consider the potential benefits of a single-dose treatment given in the office for

Young and/or uncooperative children



People with autism spectrum disorders or other sensory issues



Older adults with reduced dexterity, neurodegenerative conditions, or cognitive/memory issues

Patients with unresolved AOE

AOE, acute otitis externa; HCP, healthcare professional.

References: 1. Data on file, Otonomy, Inc. **2.** England RJA, Homer JJ, Jasser P, Wilde AD. Accuracy of patient self-medication with topical eardrops. *J Laryngol Otol*. 2000;114(1):24-25. doi:10.1258/0022215001903834 **3.** Otiprio. Prescribing information. Otonomy, Inc; Rev. 2018. **4.** Schaeffer P, Baugh RF. Acute otitis externa: an update. *Am Fam Physician*. 2012;86(11):1055-1061. **5.** Ansley J, Mair EA, Namini H, Lu CH, LeBel C. OTO-201 for the treatment of acute otitis externa: results from a phase 3 randomized clinical study. *Ann Otol Rhinol Laryngol*. 2019;128(6):524-533. doi:10.1177/0003489419830116 **6.** Mair EA, Park AH, Don D, Koempel J, Bear M, LeBel C. Safety and efficacy of intratympanic ciprofloxacin otic suspension in children with middle ear effusion undergoing tympanostomy tube placement: two randomized clinical trials. *JAMA Otolaryngol Head Neck Surg*. 2016;142(5):444-451. doi:10.1001/jamaoto.2016.0001 **7.** Park AH, White DR, Moss JR, Bear M, LeBel C. Phase 3 trials of thermosensitive ciprofloxacin gel for middle ear effusion in children with tubes. *Otolaryngol Head Neck Surg*. 2016;155(2):324-331. doi:10.1177/0194599816645526

IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

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ALK OTONOMY®

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