Augmentin *ES*™

Amoxicillin as trihydrate 600 mg/5 ml
Clavulanic Acid as potassium salt 42.9 mg/5 ml

Acute otitis media (AOM) is one of the most common diseases of childhood affecting more than 80% of children by the age of 5 years[1]

Children with otitis media present with clinical manifestations such as[2]

- Ear pain and rubbing
- Fever
- Excessive crying
- Rhinitis

Pulling of ear is not a clear clinical manifestation of AOM or otitis media with effusion (OME)[2]

- AOM is a visual diagnosis based on viewing the tympanic membrane[2]

Complications of otitis media may include[3]

- Intratemporal suppurative complications such as mastoiditis
- Intracranial suppurative complications such as meningitis
- Mild to moderate hearing loss which may result in poorer verbal skills later[3]

Clinical Practice Guideline: The diagnosis and management of acute otitis media

American Academy of Pediatrics 2013[4]

- Pain associated with AOM can be substantial and a treatment to reduce pain is recommended
- Antibiotic therapy for initial management for severe uncomplicated AOM after accurate diagnosis is recommended
- Antibiotic therapy or additional observation for initial management of non-severe uncomplicated AOM after accurate diagnosis is recommended

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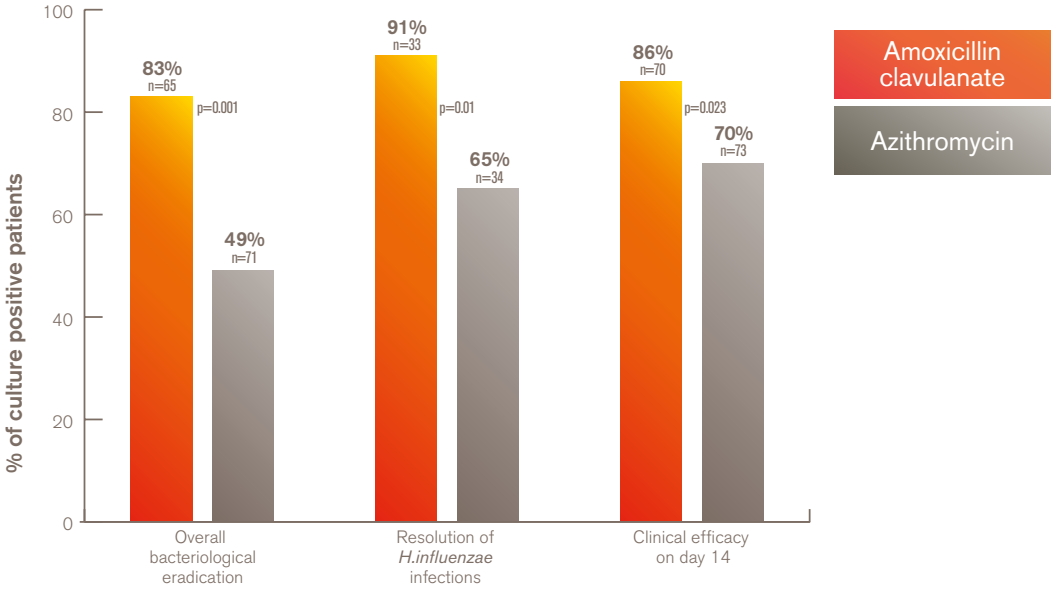
Amoxicillin clavulanate

- Rapidly and extensively penetrates into the middle ear fluid (MEF) of pediatric patients with AOM[5]
- Achieves MEF concentrations that exceed MIC_{90} of common causative pathogens in AOM such as *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis*[5]*
- Effectively reduced the duration of middle ear effusion (MEE), the risk for persistent MEE and possible concomitant hearing impairment in children with AOM[6]

Patients treated with macrolides (such as azithromycin or clarithromycin) for AOM may be more likely to have clinical failures[7]

Bacteriologic and clinical efficacy of amoxicillin clavulanate vs. azithromycin in AOM[8]



A single blind study of 238 infants and children with AOM randomized to receive amoxicillin clavulanate (45/6.4 mg/kg/day in two divided doses for 10 days) or azithromycin (10 mg/kg on Day 1, then 5 mg/kg daily on Days 2 through 5). Tympanocentesis was performed before the first dose and repeated on Day 4, 5 or 6. Clinical response was assessed at end of therapy between Days 12 and 14 and at follow-up between Days 22 and 28.

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Amoxicillin clavulanate† (90 mg/kg per day of amoxicillin, with 6.4 mg/kg per day of clavulanate [amoxicillin to clavulanate ratio, 14:1] in 2 divided doses) is recommended first line treatment for

- Initial immediate or delayed antibiotic treatment
- Antibiotic treatment after 48-72 hours of failure of initial antibiotic treatment

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*Susceptibility patterns may vary with time and geography, please refer to local susceptibility data before prescribing
†May be considered in patients who have received amoxicillin in the previous 30 days or who have the otitis-conjunctivitis syndrome

Dosage and Administration[9]

Augmentin *ES™* is indicated for the treatment of Acute otitis media in children aged at least 3 months and less than 40 kg body weight, caused or thought likely to be caused by penicillin-resistant *Streptococcus pneumoniae*

Augmentin ES Amoxicillin as trihydrate 600 mg/5 ml, Clavulanic Acid as potassium salt 42.9 mg/5 ml

The recommended daily dose is 90/6.4 mg/kg/day in two divided doses

Children < 40 kg (aged ≥ 3 months)

Body Weight (kg)	Volume of Augmentin ES™ providing 90/6.4 mg/kg/day
8	3.0 ml twice daily
12	4.5 ml twice daily
16	6.0 ml twice daily
20	7.5 ml twice daily
24	9.0 ml twice daily
28	10.5 ml twice daily
32	12.0 ml twice daily
36	13.5 ml twice daily

Augmentin (amoxicillin clavulanate) safety information[9]

- Contraindicated in patients with known hypersensitivity to beta-lactam antibiotics (penicillins and cephalosporins)
- Gastrointestinal disturbances are common
- Prolonged use may result in overgrowth of non-susceptible organisms

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Adverse events reporting service: il.safety@gsk.com, Tel: 03-9297100

ל -PI המלא נא ללחוץ כאן

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9. Augmentin PI approved by the MOH

*The image is shown is for representational purposes only

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