

EMLc
ATC codes: [J01CR02](#)

Indication	Acute otitis media ICD11 code: AB00
INN	Amoxicillin + clavulanic acid
Medicine type	Chemical agent
Antibiotic groups	A ACCESS
List type	Core
Formulations	Parenteral > General injections > IV: 500 mg (as sodium salt) + 100 mg (as potassium salt) powder for injection ; 1000 mg (as sodium salt) + 200 mg (as potassium salt) powder for injection Oral > Liquid: 125 mg + 31.25 mg powder for oral liquid (EMLc) ; 250 mg + 62.5 mg powder for oral liquid (EMLc) Oral > Solid: 500 mg (as trihydrate) + 125 mg (as potassium salt)
EML status history	First added in 2017 (TRS 1006)
Sex	All
Age	Also recommended for children
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Patents have expired in most jurisdictions Read more about patents . 
Wikipedia	Amoxicillin + clavulanic acid 
DrugBank	Amoxicillin  , Clavulanic acid (Clavulanate) 

Expert Committee recommendation

The Expert Committee noted that the appropriate first-line treatment option for otitis media is watchful waiting, symptom relief and no antibiotic treatment, unless a child is under 2 years of age with bilateral otitis media. The Committee endorsed the inclusion of amoxicillin as first-choice therapy and amoxicillin + clavulanic acid as second-choice therapy in suspected bacterial otitis media.

Background

Acute otitis media is one of the most common infections in children. There has been controversy about the best approach, that is, whether otitis media should include early therapy or watchful waiting. On the one hand, avoidance of antibiotics could reduce resistance, adverse events and cost; on the other, concern has been raised about suppurative complications of otitis media if left untreated.

Summary of evidence

A 2015 Cochrane review of 13 randomized controlled trials (RCTs; 3401 children) showed that antibiotics had not reduced pain at 24 hours after the start of treatment (risk ratio (RR) 0.89; 95% confidence interval (CI) 0.78–1.01) but almost a third fewer treated children had residual pain at 2–3 days (RR 0.70; 95% CI 0.57–0.86) (1). Immediate treatment with antibiotics was not associated with a reduction in the number of children with pain (RR 0.91, 95% CI 0.75 to 1.10) compared with expectant observation. Antibiotics did reduce the number of children with tympanic membrane perforations (RR 0.37; 95% CI 0.18–0.76) but

not abnormal tympanometry at 3 months (RR 0.97; 95% CI 0.76–1.24) or the number of children with late acute otitis media recurrences (RR 0.93; 95% CI 0.78–1.10). Adverse events such as vomiting, diarrhoea and rash occurred more often in children taking antibiotics than in placebo-treated children (RR 1.38; 95% CI 1.19–1.59). A 2013 Cochrane review (5 RCTs, 1601 children) showed that one or two daily doses of amoxicillin, with or without clavulanic acid, were comparable to three or four doses for clinical cure at the end of therapy (RR 1.03; 95% CI 0.99–1.07), during therapy (RR 1.06; 95% CI 0.85–1.33) and at follow-up (RR 1.02; 95% CI 0.95–1.09) (2).

Guidelines

Guidelines of the American Academy of Pediatrics and Family Physicians and of the Canadian Paediatric Society recommend treatment of acute otitis media in children with significant pain for longer than 48 hours and/or fever of 39 °C or higher (3, 4). The Canadian Paediatric Society guidelines recommend amoxicillin as the antibiotic of choice when it is felt that acute otitis media should be treated with antibiotics (3). The American Academy of Pediatrics and Family Physicians recommend amoxicillin (but suggest amoxicillin + clavulanic acid if a child has already been exposed to amoxicillin in the previous 30 days) and cephalosporins for patients with allergy to penicillin (cefdinir, cefuroxime, cefpodoxime and ceftriaxone) (4).

Rationale for antibiotic selection

Antibiotics may not be needed for otitis media and a strategy of watchful waiting may reduce unnecessary antibiotic use. Unless a child is under 2 years of age with bilateral otitis media (4), no antibiotics is a perfectly reasonable first-line option. Amoxicillin is the core antibiotic choice; amoxicillin + clavulanic acid is another option. Cefuroxime or ceftriaxone can be used for severe cases, minimizing exposure to third-generation cephalosporins.

Committee considerations

For common community-acquired infections, the main focus has been on empirical treatment choices that are broadly applicable in most countries. Generally, alternatives for use in case of allergy were not considered. The Expert Committee considered the various antibiotics proposed in the application under the guiding principle of parsimony and selected first- and second-choice antibiotics for this indication for inclusion on the EML and/or EMLc. Ceftriaxone and cefuroxime were excluded. Recommended first- and second-choice antibiotics are reported above. The first-choice antibiotics are those generally recommended on the basis of available evidence and are usually narrow-spectrum agents.

EML recommendations: Acute otitis media

First choice

amoxicillin

Second choice

amoxicillin + clavulanic acid

1. Venekamp RP, Sanders SL, Glasziou PP, Del Mar CB, Rovers MM. Antibiotics for otitis media in children. Cochrane Database Syst Rev. 2015;(6):CD000219.

2. Thanaviratnanich S, Laopaiboon M, Vatanasapt P. Once or twice daily versus three times daily amoxicillin with or without clavulanic acid for the treatment of acute otitis media. Cochrane Database Syst Rev. 2013;(12):CD004975.

3. Le Saux N, Robinson JL, Canadian Paediatric Society, Infectious Diseases and Immunization Committee. Management of acute otitis media in children six months of age and older. Paediatr Child Health. 2016;21(1):39–50.

4. Lieberthal AS, Carroll AE, Chonmaitree T, Ganiats TG, Hoberman A, Jackson MA et al. The diagnosis and management of acute otitis media. Pediatrics. 2013;131(3):e964–99.

