Amoxicillin + clavulanic acid


**EMLc**

**ATC codes:** J01CR02

### Indication
- **Acute otitis media**
- **ICD11 code:** AB00

### INN
- Amoxicillin + clavulanic acid

### Medicine type
- Chemical agent

### Antibiotic groups
- 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)

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**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...
Guidelines

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

<table>
<thead>
<tr>
<th>First choice</th>
<th>Second choice</th>
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<tbody>
<tr>
<td>amoxicillin</td>
<td>amoxicillin + clavulanic acid</td>
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