6. Anti-infective medicines

6.2. Antibacterials

6.2.1. Access group antibiotics

### Gentamicin

**Indication:** Bacterial pneumonia

**INN:** Gentamicin

**Medicine type:** Chemical agent

**Antibiotic groups:** ACCESS

**List type:** Core (EML) (EMLc)

**Formulations:**
- Parenteral > General injections > unspecified: 10 mg per mL in 2 mL vial (as sulfate); 40 mg per mL in 2 mL vial (as sulfate)

**EML status history:**
- First added in 2017 (TRS 1006)
- Changed in 2021 (TRS 1035)
- Changed in 2023 (TRS 1049)

**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:** Gentamicin

**DrugBank:** Gentamicin

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**Expert Committee recommendation**

1. Application for the addition of amoxicillin + clavulanic acid 200 mg + 28.5 mg dispersible tablet to the core list of the EMLc for the same indications for which other formulations of amoxicillin + clavulanic acid are currently listed. The Expert Committee recognized the importance of age-appropriate formulations of essential medicines to better meet the dosing needs of children. The Committee noted that the 7:1 ratio of amoxicillin to clavulanic acid is associated with similar efficacy to the 4:1 ratio but has a reduced frequency of gastrointestinal adverse effects. The dispersible tablet formulation also offers advantages over oral liquid formulations for ease of administration and heat stability. The Committee therefore recommended the inclusion of the 200 mg + 28.5 mg dispersible tablet formulation of amoxicillin + clavulanic acid as an Access group antibiotic on the core list of the EMLc for treatment of bacterial infections in children – specifically those infections for which amoxicillin + clavulanic acid is already recommended on the EMLc.

2. Review of the age-appropriateness of formulations of essential medicines for children.

In consideration of the review of the age appropriateness of formulations of medicines on the EMLc, and the comparison report of the EML versus EMLc, the Expert Committee recommended changes to the EMLc for addition of new, age-appropriate formulations and strengths of existing essential medicines, deletion of unavailable or age-inappropriate formulations and strengths, and other listing modifications as proposed in the application. The Committee also endorsed the proposals for further review of the public health relevance and evidence for specific medicines for use in children for potential future consideration for inclusion on the EMLc. The Committee noted and welcomed the ongoing review being coordinated by the Secretariat for the remaining sections of the EMLc for consideration by the 2025 Expert Committee. As a result of the review of the age-appropriateness of formulations on the EMLc, the Expert Committee recommended:
- the addition of a new formulation of amoxicillin (dispersible, scored tablet, 250 mg and 500 mg) to the EMLc.
- the addition of new strength formulations of cefotaxime (powder for injection: 500 mg; 1 g; 2 g (as...
Summary of evidence

1. Application for the addition of amoxicillin + clavulanic acid 200 mg + 28.5 mg dispersible tablet to the core list of the EMLc for the same indications for which other formulations of amoxicillin + clavulanic acid are currently listed. The public health relevance of age-appropriate formulations of essential medicines for children is well established. The Global Accelerator for Paediatric Formulations was developed in response to the World Health Assembly resolution 69.20 on promoting innovation and access to high quality medicines for children. In the 2022–2024 strategy, the Global Accelerator for Paediatric Formulations clearly stated that the development of dispersible tablets over bulky syrups or the enabling of formulary consolidation with flexible dosage forms should be one of the priority tasks (2). Multiple amoxicillin + clavulanic acid formulations in a 4:1 ratio are included on the EMLc as first- or second-choice empiric treatment for various bacterial infections. • First choice: community-acquired pneumonia, complicated intra-abdominal infections, hospital acquired pneumonia, low-risk febrile neutropenia, lower urinary tract infections, sinusitis, and skin and soft tissue infections. • Second choice: bone and joint infections, community-acquired pneumonia, otitis media and surgical prophylaxis. In 2021, a higher strength formulation of amoxicillin + clavulanic acid in a 7:1 ratio (875 mg + 125 mg) was recommended for inclusion on the EML for treatment of community-acquired pneumonia and intra-abdominal infections in adults. In making its recommendation, the Expert Committee noted that a higher ratio of amoxicillin to clavulanic acid is generally associated with less diarrhoea, a recognized adverse effect of this combination (1). Amoxicillin + clavulanic acid 200 mg + 28.5 mg dispersible tablet is not currently available in any markets. It has regulatory approval in Malawi. Submissions made to regulatory authorities for Kenya, Rwanda and Uganda are pending approval. ====
Guidelines

Committee considerations

EML recommendations: Bacterial pneumonia

First choice

Second choice

COMMUNITY-ACQUIRED PNEUMONIA - MILD TO MODERATE

(RR 0.70, 95% CI 0.48 to 1.00); skin adverse events (RR 0.72, 95% CI 0.44 to 1.17) or compliance rate (RR 1.05, 95% CI 0.98 to 1.13). An observer-blinded, multicentre study conducted in the 1990s randomized 437 children aged 2–12 years with lower respiratory tract infections to receive 7 days of treatment with amoxicillin + clavulanic acid either twice daily in a 7:1 ratio or three times daily in a 4:1 ratio (7). Both regimens had similar clinical success (cure) rates (81.0% and 77.8%, respectively). Both regimens were well tolerated, and no statistically significant difference was found in the incidence of adverse events between the two groups. Compliance with study medication was high and similar for both groups (80% compliance was 90.0% and 87.0% for the twice-daily and three-times-daily groups, respectively). The safety profile of amoxicillin + clavulanic acid is well known. In children, the most frequently reported adverse events are mild gastrointestinal disturbances, with diarrhoea being largely attributed to clavulanic acid. In the trials with a direct comparison between amoxicillin + clavulanic acid 4:1 versus 7:1 ratios, no significant difference was seen in the safety profile of the two products overall. Some trials reported a significantly lower incidence of diarrhoea in the twice-daily 7:1 groups, which is plausible due to the lower dose of clavulanic acid administered (3,4,8). The price of the proposed product is reported in the application as US$ 2.05 per pack of 32 dispersible tablets (US$ 0.064 per tablet). Indicative prices for amoxicillin + clavulenic acid 4:1 formulations included in the UNICEF supply catalogue are: • 250 mg/62.5 mg dispersible tablet: US$ 5.06 per pack of 50 tablets (US$ 0.10 per tablet); • 125 mg/31.25 mg powder for oral suspension: US$ 1.87 per 100 mL bottle (US$ 0.09 per 125 mg amoxicillin dose).
COMMUNITY-ACQUIRED PNEUMONIA - SEVERE [CHILDREN]

- amoxicillin
  co-prescribed with gentamicin
- benzylpenicillin
  co-prescribed with gentamicin
- amoxicillin + clavulanic acid
- cefotaxime
- ceftriaxone
  co-prescribed with clarithromycin
- amoxicillin
  co-prescribed with gentamicin

COMMUNITY-ACQUIRED PNEUMONIA - SEVERE

- cefotaxime
  co-prescribed with clarithromycin
- amoxicillin + clavulanic acid
  co-prescribed with clarithromycin
- ceftriaxone
  co-prescribed with clarithromycin

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1. Application for the addition of amoxicillin + clavulanic acid 200 mg + 28.5 mg dispersible tablet to the core list of the EMLc for the same indications for which other formulations of amoxicillin + clavulanic acid are currently listed.


