Dosing

Pediatric Note: Dosing based on amoxicillin component; dose and frequency are product specific; not all products are interchangeable, using a product with the incorrect amoxicillin:clavulanate ratio could result in subtherapeutic clavulanate concentrations or severe diarrhea.

General dosing, susceptible infection:

• 2:1 formulations are dosed 3 times daily (amoxicillin to clavulanate ratio could result in subtherapeutic clavulanate concentrations or severe diarrhea).

• 5:1 formulation:

  - Immediate-release formulations: 25 mg amoxicillin/kg/dose every 12 hours.
  - Extended-release formulation (16:1): 25 to 45 mg amoxicillin/kg/day in divided doses twice daily; maximum dose: 4,000 mg/day.
  - 10:1 formulation: 50 mg amoxicillin/kg/dose every 12 hours.

• Pediatric Note: Dosing based on amoxicillin component; dose and frequency are product specific; not all products are interchangeable; using a product with the incorrect amoxicillin:clavulanate ratio could result in subtherapeutic clavulanate concentrations or severe diarrhea.

  - Frequency of dosing generally based on ratio of amoxicillin to clavulanate:
    - 2:1 formulations are dosed 3 times daily (amoxicillin 250 mg/clavulanate 125 mg). Note: Per the manufacturer, the amoxicillin 250 mg/clavulanate 125 mg tablet should only be used in patients ≥40 kg due to the amoxicillin to clavulanate ratio.
    - 4:1 formulations are dosed 3 times daily (amoxicillin 125 mg/clavulanate 31.25 mg, amoxicillin 250 mg/clavulanate 62.5 mg, amoxicillin 500 mg/clavulanate 125 mg).
    - 7:1 formulations are dosed 2 times daily (amoxicillin 200 mg/clavulanate 28.5 mg, amoxicillin 400 mg/clavulanate 57 mg, amoxicillin 875 mg/clavulanate 125 mg).
    - 14:1 formulations are dosed 2 times daily (amoxicillin 600 mg/clavulanate 42.9 mg).
    - 16:1 formulations (extended release) are dosed 2 times daily (amoxicillin 1,000 mg/clavulanate 62.5 mg).

• General dosing, susceptible infection: Note: Dosing determined by formulations amoxicillin:clavulanate ratio:

  - Immediate-release formulations (Red Book [AAP 2011]): Infants, Children, and Adolescents: Oral:
    - 4:1 formulation: 20 to 40 mg amoxicillin/kg/day in divided doses 3 times daily; maximum daily dose: 1,500 mg/day.
    - 7:1 formulation: 25 to 45 mg amoxicillin/kg/day in divided doses twice daily; maximum daily dose: 1,750 mg/day.
    - 14:1 formulation: single dose: 90 mg amoxicillin/kg/day in divided doses twice daily; maximum daily dose: 4,000 mg/day.
  - Extended-release formulation (16:1): Children and Adolescents >40 kg: 2,000 mg amoxicillin every 12 hours.

• Impetigo: Infants, Children, and Adolescents: Oral: 25 mg amoxicillin/kg/day in divided doses twice daily; maximum dose: 875 mg amoxicillin/day (IDSA [Stevens 2014]).

• Otitis media, acute: Infants ≥3 months and Children: Oral: 90 mg amoxicillin/0.5 mL intranasal suspension; 120 mg amoxicillin oral suspension (600 mg/mL): Oral: 90 mg amoxicillin/day divided every 12 hours for up to 10 days; recommended for use in children with severe illness, who have received amoxicillin in the past 30 days, who have treatment failure at 48 to 72 hours on first-line therapy, and when coverage for beta-lactamase positive H. influenzae and M. catarrhalis is needed. Variable duration of therapy; the manufacturer suggests 10- day course in all patients; however, new data suggests a shorter course in some cases: If <2 years of age or severe symptoms (any age): 10-day course; if 2 to 5 years: 7 to 10 days; if ≥6 years of age and to mild to moderate symptoms: 5-7 to 10-day course (AAP [Lieberthal 2013]).

• Pneumonia, community-acquired (IDSA/PIDS [Bradley 2011]): Infants ≥3 months, Children, and Adolescents: Empiric therapy: Oral: 90 mg amoxicillin/kg/day in divided doses twice daily; maximum daily dose: 4,000 mg/day.

  - H. influenzae, beta-lactamase positive strains, mild infection, or step-down therapy: Oral: Standard dose: 45 mg amoxicillin/kg/day in divided doses 3 times daily.

  - High dose: 90 mg amoxicillin/kg/day in divided doses twice daily.

• Rhinosinusitis, acute bacterial:

  - Infants ≤3 months: Oral: 45 mg amoxicillin/kg/day divided every 12 hours or 40 mg/kg/day divided every 8 hours.

  - Children and Adolescents: Oral:
    - Standard dose: 45 mg amoxicillin/kg/day divided every 12 hours for 10 to 14 days; usual adult dose: 875 mg amoxicillin/dose (IDSA [Chow 2012]).
    - High dose: 80 to 90 mg amoxicillin/kg/day divided every 12 hours; maximum dose: 2,000 mg/dose (AAP [Wald 2013]; IDSA [Chow 2012]); treatment duration variable: 10 to 28 days, some have suggested discontinuation of therapy 7 days after resolution of signs and symptoms of infection (AAP [Wald 2013]); some experts recommend a duration of 10 to 14 days (IDSA [Chow 2012]). Note: Recommended for patients who live in areas with high endemic rates of penicillin-nonsusceptible S. pneumoniae.

• Urinary tract infections: Infants ≥2 months and Children ≤5 years: Oral: 20 to 40 mg amoxicillin/kg/day in divided doses 3 times daily (AAP 2011).

• IV dosing (Canadian labeling; not available in US):

  - Note: Choice of formulation depends upon desired dosages of amoxicillin and clavulanate; for higher daily doses of amoxicillin (as may be used in the empiric coverage of Streptococcus pneumoniae), the 10:1 formulation is preferred to avoid unnecessary high clavulanate exposure.
  - Infants <3 months or weighing <4 kg: IV: 25 mg amoxicillin/kg/day every 12 hours.

  - Infants ≥3 months weighing ≥4 kg, Children, and Adolescents: IV: 25 mg amoxicillin/kg/day every 8 hours; maximum dose: 1,000 mg amoxicillin/kg/day.

  - 10:1 formulation: Infants <3 months or weighing <4 kg: IV: 25 mg amoxicillin/kg/day every 12 hours.

  - Infants ≥3 months weighing ≥4 kg, Children, and Adolescents: IV: 25 mg amoxicillin/kg/day every 8 hours; maximum dose: 2,000 mg amoxicillin/kg/day.