# Augmentin Chewable Tablets, Powder for Oral Suspension, and Tablets (amoxicillin/clavulanate potassium) - Drug Summary

Dr. Reddy's Laboratories Inc

Jump to Section
- THERAPEUTIC CLASS
- DEA CLASS
- ADULT DOSAGE & INDICATIONS
- PEDIATRIC DOSAGE & INDICATIONS
- DOSING CONSIDERATIONS
- View All Sections...

Related Drug Information



## Augmentin (amoxicillin/clavulanate potassium)

## THERAPEUTIC CLASS

Aminopenicillin/beta lactamase inhibitor

## DEA CLASS

RX

## ADULT DOSAGE & INDICATIONS

### General Dosing

**Usual:** One 500mg tab q12h or one 250mg tab q8h
**Severe Infections:** One 875mg tab q12h or one 500mg tab q8h

### Lower Respiratory Tract Infections

**Usual:** One 875mg tab q12h or one 500mg tab q8h

### Other Indications

Skin and skin structure infections
UTIs
Acute bacterial otitis media
Sinusitis

## PEDIATRIC DOSAGE & INDICATIONS

### General Dosing

**<12 Weeks of Age:**
**Usual:** 30mg/kg/day divided q12h (125mg/5mL sus)

**≥12 Weeks of Age:**
**Less Severe Infections:**
25mg/kg/day q12h (200mg/5mL or 400mg/5mL sus; 200mg or 400mg chewable tab) or 20mg/kg/day q8h (125mg/5mL or 250mg/5mL sus; 125mg or 250mg chewable tab)
**Severe Infections:**
45mg/kg/day q12h (200mg/5mL or 400mg/5mL sus; 200mg or 400mg chewable tab) or 40mg/kg/day q8h (125mg/5mL or 250mg/5mL sus; 125mg or 250mg chewable tab)
**≥40kg:**
Use adult dose

### Otitis Media

**≥12 Weeks of Age:**
45mg/kg/day q12h (200mg/5mL or 400mg/5mL sus; 200mg or 400mg chewable tab) or 40mg/kg/day q8h (125mg/5mL or 250mg/5mL sus; 125mg or 250mg chewable tab) for 10 days

### Sinusitis

**≥12 Weeks of Age:**
45mg/kg/day q12h (200mg/5mL or 400mg/5mL sus; 200mg or 400mg chewable tab) or 40mg/kg/day q8h

(125mg/5mL or 250mg/5mL sus; 125mg or 250mg chewable tab)

### Lower Respiratory Tract Infections

**≥12 Weeks of Age:**
45mg/kg/day q12h (200mg/5mL or 400mg/5mL sus; 200mg or 400mg chewable tab) or 40mg/kg/day q8h (125mg/5mL or 250mg/5mL sus; 125mg or 250mg chewable tab)

## DOSING CONSIDERATIONS

**Renal Impairment**
**GFR <30mL/min:** Do not give the 875mg dose
**GFR 10-30mL/min:** 500mg or 250mg q12h
**GFR <10mL/min:** 500mg or 250mg q24h
**Hemodialysis:** 500mg or 250mg q24h; give additional dose during and at the end of dialysis

## ADMINISTRATION

Oral route

Doses are based on amoxicillin component
Take w/ or w/o food
Take at start of a meal to reduce GI intolerance

**Sus**
Shake well before use
Reconstituted sus must be stored under refrigeration and discarded after 10 days
Refer to PI for mixing directions

**Adults:**
May use 125mg/5mL or 250mg/5mL sus in place of 500mg tab
May use 200mg/5mL or 400mg/5mL sus in place of 875mg tab

## HOW SUPPLIED

(Amoxicillin-Clavulanic Acid) Sus: 125mg-31.25mg/5mL, 250mg-62.5mg/5mL [75mL, 100mL, 150mL], 200mg-28.5mg/5mL, 400mg-57mg/5mL [50mL, 75mL, 100mL]; Tab: 250mg-125mg, 500mg-125mg, 875mg-125mg*; Tab, Chewable: 125mg-31.25mg, 200mg-28.5mg, 250mg-62.5mg, 400mg-57mg *scored

## CONTRAINDICATIONS

History of amoxicillin/clavulanate-associated cholestatic jaundice/hepatic dysfunction.

## WARNINGS/PRECAUTIONS

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions reported; d/c if an allergic reaction occurs and institute appropriate therapy. Hepatic dysfunction, including hepatitis and cholestatic jaundice, may occur. *Clostridium difficile*-associated diarrhea (CDAD) reported; d/c if CDAD is suspected or confirmed. Avoid with mononucleosis. May result in bacterial resistance with prolonged use in the absence of a proven/suspected bacterial infection; take appropriate measures if superinfection develops. The 200mg and 400mg chewable tabs and 200mg/5mL and 400mg/5mL sus contain phenylalanine; avoid with phenylketonurics. The 250mg tab and 250mg chewable tab are not interchangeable due to unequal clavulanic acid amounts; do not use 250mg tab in pediatric patients until child weighs at least 40kg. Do not substitute two 250mg tabs for one 500mg tab. May decrease estrogen levels in pregnant women. Lab test interactions may occur. Caution in elderly.

## ADVERSE REACTIONS

Diarrhea/loose stools, nausea, skin rashes, urticaria

## DRUG INTERACTIONS

Probenecid may increase/prolong levels of amoxicillin; coadministration not recommended. Abnormal prolongation of PT (increased INR) reported with oral anticoagulants; may require oral anticoagulant dose adjustment. Allopurinol may increase incidence of rashes. May reduce efficacy of combined oral estrogen/progesterone contraceptives.

## PREGNANCY AND LACTATION

Category B, caution in nursing.

## MECHANISM OF ACTION

Amoxicillin: Aminopenicillin; semisynthetic antibiotic with broad spectrum of bactericidal activity against gram-positive and gram-negative organisms. Clavulanate: β-lactamase inhibitor; possesses ability to inactivate a wide range of β-lactamase enzymes commonly found in microorganisms resistant to penicillin (PCN) and cephalosporins.

## PHARMACOKINETICS

**Absorption:** Refer to PI for absorption parameters. **Distribution:** Plasma protein binding: Amoxicillin (18%); clavulanic acid (25%). Amoxicillin: Found in breast milk. **Elimination:** Amoxicillin: Urine (50-70% unchanged); $T_{1/2}$=1.3 hrs. Clavulanic Acid: Urine (25-40% unchanged); $T_{1/2}$=1 hr.

## ASSESSMENT

Assess for history of serious hypersensitivity reactions to other β-lactam antibacterial drugs (eg, PCN, cephalosporins) or other allergens, history of amoxicillin/clavulanate-associated cholestatic jaundice/hepatic dysfunction, hepatic/renal impairment, mononucleosis, phenylketonuria, pregnancy/nursing status, and possible drug interactions.

## MONITORING

Monitor for anaphylactic reactions, superinfection, skin rash, CDAD, and other adverse reactions. Periodically monitor renal (especially in elderly) and hepatic function. Monitor PT/INR with oral anticoagulants.

## PATIENT COUNSELING

Instruct to take each dose with a meal or snack to reduce possibility of GI upset. Counsel that drug only treats bacterial, not viral (eg, common cold), infections. Instruct to take ud; inform that skipping doses or not completing the full course of therapy may decrease effectiveness of the drug and increase resistance of bacteria. Advise to consult physician if severe diarrhea or watery/bloody stools occur (even as late as ≥2 months after treatment). Instruct to use a dosing spoon or medicine dropper when dosing a child with sus, and rinse measuring device after each use. Instruct to discard any unused medicine.

## STORAGE

≤25°C (77°F).

Back to top