Amoxicillin Tablets (amoxicillin) - Drug Summary

Teva Pharmaceuticals USA Inc

Related Drug Information

Amoxicillin (amoxicillin)

COMMON BRAND NAMES

Amoxil (Discontinued), Trimox (Discontinued), Amoxicillin

THERAPEUTIC CLASS

Semisynthetic ampicillin derivative

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Helicobacter pylori Eradication

W/ (Active or 1-Year History) Duodenal Ulcer Disease:
Dual Therapy: 1g + 30mg lansoprazole, each q8h for 14 days
Triple Therapy: 1g + 30mg lansoprazole + 500mg clarithromycin, all q12h for 14 days

Ear/Nose/Throat Infection

Mild/Moderate: 500mg q12h or 250mg q8h
Severe: 875mg q12h or 500mg q8h

Genitourinary Tract Infections

Mild/Moderate: 500mg q12h or 250mg q8h
Severe: 875mg q12h or 500mg q8h

Skin and Skin Structure Infections

Mild/Moderate: 500mg q12h or 250mg q8h
Severe: 875mg q12h or 500mg q8h

Lower Respiratory Tract Infections

Mild/Moderate or Severe: 875mg q12h or 500mg q8h

Treatment Duration

Continue for a minimum of 48-72 hrs beyond the time the patient becomes asymptomatic or evidence of bacterial eradication has been obtained

***Streptococcus pyogenes* Infections:** Treat for at least 10 days

PEDIATRIC DOSAGE & INDICATIONS

Lower Respiratory Tract Infections

≤12 Weeks of Age:
Max: 30mg/kg/day divided q12h

>3 Months of Age:
<40kg: 45mg/kg/day divided q12h or 40mg/kg/day divided q8h
≥40kg: 875mg q12h or 500mg q8h

Ear/Nose/Throat Infection

≤12 Weeks of Age:
Max: 30mg/kg/day divided q12h

>3 Months of Age:
<40kg:
Mild/Moderate: 25mg/kg/day divided q12h or 20mg/kg/day divided q8h
Severe: 45mg/kg/day divided q12h or 40mg/kg/day divided q8h
≥40kg:
Mild/Moderate: 500mg q12h or 250mg q8h
Severe: 875mg q12h or 500mg q8h

Genitourinary Tract Infections

≤12 Weeks of Age:
Max: 30mg/kg/day divided q12h

>3 Months of Age:
<40kg:
Mild/Moderate: 25mg/kg/day divided q12h or 20mg/kg/day divided q8h
Severe: 45mg/kg/day divided q12h or 40mg/kg/day divided q8h
≥40kg:
Mild/Moderate: 500mg q12h or 250mg q8h
Severe: 875mg q12h or 500mg q8h

Skin and Skin Structure Infections

≤12 Weeks of Age:
Max: 30mg/kg/day divided q12h

>3 Months of Age:
<40kg:
Mild/Moderate: 25mg/kg/day divided q12h or 20mg/kg/day divided q8h
Severe: 45mg/kg/day divided q12h or 40mg/kg/day divided q8h
≥40kg:
Mild/Moderate: 500mg q12h or 250mg q8h
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Treatment Duration

Continue for a minimum of 48-72 hrs beyond the time that patient becomes asymptomatic or evidence of bacterial eradication has been obtained

***Streptococcus pyogenes* Infections:** Treat for at least 10 days

DOSING CONSIDERATIONS

Renal Impairment
Adults:
GFR <30mL/min: Should not receive a 875mg dose
GFR 10-30mL/min: 250mg or 500mg q12h, depending on severity of infection
GFR <10mL/min: 250mg or 500mg q24h, depending on severity of infection
Hemodialysis: 250mg or 500mg q24h, depending on severity of infection; give an additional dose during and at end of dialysis

ADMINISTRATION

Oral route

Sus
125mg/5mL: Reconstitute 80mL, 100mL, or 150mL bottle size w/ 62mL, 77mL, or 113mL of water respectively.
200mg/5mL: Reconstitute 50mL, 75mL, or 100mL bottle size w/ 39mL, 57mL, or 75mL of water respectively.
250mg/5mL: Reconstitute 80mL, 100mL, or 150mL bottle size w/ 47mL, 60mL, or 90mL of water respectively.
400mg/5mL: Reconstitute 50mL, 75mL, or 100mL bottle size w/ 35mL, 51mL, or 67mL of water respectively.
Add approximately 1/3 of the total amount of water to wet powder, then shake vigorously.
Add the remainder of the water and shake vigorously.
Place directly on tongue for swallowing.
Can be added to formula, milk, fruit juice, water, ginger ale, or cold drinks; take immediately.
Shake well before use.
Discard any unused portion of the reconstituted sus after 14 days; refrigeration is preferable, but not required.

HOW SUPPLIED

Cap: 250mg, 500mg; **Sus:** 125mg/5mL [80mL, 100mL, 150mL], 200mg/5mL [50mL, 75mL, 100mL], 250mg/5mL [80mL, 100mL, 150mL], 400mg/5mL [50mL, 75mL, 100mL]; **Tab:** 500mg, 875mg*; **Tab, Chewable:** 125mg, 250mg *scored

WARNINGS/PRECAUTIONS

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions reported w/ penicillin (PCN) therapy; increased risk w/ a history of PCN hypersensitivity and/or history of sensitivity to multiple allergens. *Clostridium difficile*-associated diarrhea (CDAD) reported; may need to d/c if CDAD is suspected or confirmed. Avoid use w/ mononucleosis; erythematous skin rash may develop in these patients. May result in bacterial resistance if used in the absence of a proven/suspected bacterial indication. Lab test interactions may occur. Caution in elderly; monitor renal function.

ADVERSE REACTIONS

N/V, diarrhea, rash.

DRUG INTERACTIONS

Decreased renal tubular secretion and increased/prolonged levels w/ probenecid. May reduce efficacy of combined oral estrogen/progesterone contraceptives. Chloramphenicol, macrolides, sulfonamides, and tetracyclines may interfere w/ bactericidal effects of PCN. PT prolongation (increased INR) reported w/ oral anticoagulants; dose adjustments of oral anticoagulants may be necessary. Increased incidence of rashes w/ allopurinol.

PREGNANCY AND LACTATION

Pregnancy: Category B.
Lactation: Have been shown to be excreted in human milk; may lead to sensitization of infants. Caution in nursing.

MECHANISM OF ACTION

Ampicillin analogue; has broad-spectrum bactericidal activity against susceptible organisms during active multiplication; acts through inhibition of biosynthesis of cell wall.

PHARMACOKINETICS

Absorption: Rapid. Cap: T_{max}=1-2 hrs; C_{max}=3.5-5mcg/mL (250mg), C_{max}=5.5-7.5mcg/mL (500mg). Tab: (875mg) C_{max}=13.8mcg/mL, AUC=35.4mcg•hr/mL. Sus: T_{max}=1-2 hrs (125mg/5mL, 250mg/5mL); C_{max}=1.5-3mcg/mL (125mg/5mL), C_{max}=3.5-5mcg/mL (250mg/5mL); (400mg/5mL) T_{max}=1 hr, C_{max}=5.92mcg/mL, AUC=17.1mcg•hr/mL. Tab, Chewable: (400mg) T_{max}=1 hr, C_{max}=5.18mcg/mL, AUC=17.9mcg•hr/mL. **Distribution:** Plasma protein binding (20%); found in breast milk. **Elimination:** Urine (60%, unchanged); $T_{1/2}$=61.3 min.

ASSESSMENT

Assess for history of allergic reaction to PCNs, cephalosporins, or other allergens, mononucleosis, renal function, pregnancy/nursing status, and possible drug interactions. Obtain culture and susceptibility information.

MONITORING

Monitor for serious anaphylactic reactions, erythematous skin rash, development of drug-resistant bacteria, and CDAD. Monitor renal function. Monitor PT and INR if coadministered w/ an oral anticoagulant.

PATIENT COUNSELING

Inform that drug treats only bacterial, not viral, infections. Instruct to take exactly ud; inform that skipping doses or not completing the full course of therapy may decrease effectiveness and increase resistance. Instruct to notify physician as soon as possible if watery and bloody stools (w/ or w/o stomach cramps and fever) develop, even as late as ≥2 months after having last dose. Advise patients that drug may cause allergic reactions.

STORAGE

20-25°C (68-77°F).

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