Amoxicillin (Amoxycillin)

Newborn use only

2019

<table>
<tr><td>Alert</td><td>The Antimicrobial Stewardship Team recommends this drug is listed under the following category: Unrestricted</td></tr>
<tr><td>Indication</td><td>Directed treatment of infections caused by susceptible gram positive (including Streptococcus species, Enterococcus faecalis and Listeria monocytogenes) and susceptible gram negative bacteria (some strains of Escherichia coli, non-beta-lactamase-producing Haemophilus influenzae, Neisseria meningitidis, non-penicillinase-producing strains of Proteus and Salmonellae).
Empiric treatment of suspected early onset sepsis including meningitis, with an aminoglycoside.</td></tr>
<tr><td>Action</td><td>Bactericidal – inhibits synthesis of the bacterial cell wall. Amoxicillin is hydrolysed by beta-lactamases and therefore not effective against penicillinase-producing bacteria.</td></tr>
<tr><td>Drug Type</td><td>Antibacterial – semi-synthetic, bactericidal aminopenicillin</td></tr>
<tr><td>Trade Name</td><td>Alphamox Suspension [Alphapharm], Amoxil Paediatric Drops [Aspen], Amoxil Parenteral [Aspen], Amoxil Syrup Forte Sugar Free [Aspen], Amoxil Syrup Sugar Free [Aspen], Amoxycillin Sandoz [Sandoz], APO-Amoxycillin [Apotex], Bgramin [Ascent Pharma], Chemmart Amoxycillin [Apotex], Cilamox Sugar Free Syrup [Aspen Pharma], Fisamox [Aspen], Ibiamox [Willow], Maxamox [Sandoz], Ranmoxy Granules [Ranbaxy], Terry White Chemists Amoxycillin [Apotex]</td></tr>
<tr><td>Presentation</td><td>IV: Amoxicillin sodium 500 mg and 1 g vials. Displacement volumes are 0.37 ml and 0.7 mL for 0.5 g and 1 g vials.
PO: Syrup 125 mg/5 mL and 250 mg/5 mL; Paediatric drops 100 mg/mL.</td></tr>
<tr><td>Dosage / Interval</td><td>IV
Treatment of standard infections: 50 mg/kg/dose.
Treatment of meningitis: 100 mg/kg/dose.
Dosing interval as per table below
<table>
<tr><th>Corrected Gestational Age/Postmenstrual Age</th><th>Postnatal Age</th><th>Interval</th></tr>
<tr><td>< 30+0 weeks</td><td>0–28 days</td><td>12 hourly</td></tr>
<tr><td>< 30+0 weeks</td><td>29+ days</td><td>8 hourly</td></tr>
<tr><td>30+0–36+6 weeks</td><td>0–14 days</td><td>12 hourly</td></tr>
<tr><td>30+0–36+6 weeks</td><td>15+ days</td><td>8 hourly</td></tr>
<tr><td>37+0–44+6 weeks</td><td>0–7 days</td><td>12 hourly</td></tr>
<tr><td>37+0–44+6 weeks</td><td>8+ days</td><td>8 hourly</td></tr>
</table>
PO
Treatment: 25–50 mg/kg/dose. Dose interval as follows:
<table>
<tr><th>Corrected Gestational Age/Postmenstrual Age</th><th>Postnatal Age</th><th>Interval</th></tr>
<tr><td>37^{+0}–44^{+6} weeks</td><td>0–7 days</td><td>12 hourly</td></tr>
<tr><td>37^{+0}–44^{+6} weeks</td><td>8+ days</td><td>8 hourly</td></tr>
</table>
Prophylaxis (e.g. Urinary Tract Infection): 10–15 mg/kg/dose once a day</td></tr>
<tr><td>Maximum Daily Dose</td><td>300 mg/kg/day</td></tr>
<tr><td>Route</td><td>IV
IM (only if IV route not possible as intramuscular route is painful)
PO</td></tr>
<tr><td>Preparation/Dilution</td><td>IV:
Add 4.6 mL of water for injection to the 500 mg vial for reconstitution to make 100 mg/mL solution OR
Add 9.3 mL of water for injection to the 1 g vial for reconstitution to make 100 mg/mL solution.
Further dilution (for 100 mg/kg/dose infusion IV):
Draw up 5 mL (500 mg of amoxicillin) of solution and add 5 mL sodium chloride 0.9% to make a final volume of 10mL with a concentration of 50 mg/mL.
IM:
Add 2.6 mL of water for injection to the 500 mg vial for reconstitution to make 167 mg/mL solution
PO:
1. Syrup 125 mg/5 mL: Add 87 mL water, invert the bottle and shake well. Final reconstituted suspension volume is 100 mL.</td></tr>
</table>

	2. Syrup 250 mg/5 mL: Add 87 mL water, invert the bottle and shake well. Final reconstituted suspension volume is 100 mL. 3. Paediatric drops 100 mg/mL: Add 18 mL water, invert the bottle and shake well. Final reconstituted suspension volume is 21 mL.
Administration	IV: **Infuse over 30 minutes into the proximal cannula site.** Separate from aminoglycosides by clearing the lines with a flush as penicillins inactivate them. **Doses of 100 mg/kg should be diluted to 50 mg/mL and infused over 30 minutes**. IM injection: Only if IV route is not possible. PO: The liquid preparation should be shaken well before measuring the dose. The dose may be mixed with the milk. After mixing, administer immediately.
Monitoring	Monitoring is not usually required. Follow infectious disease/microbiology advice in case of poor therapeutic response.
Contraindications	Hypersensitivity to penicillins (unlikely to be an issue in neonates).
Precautions	Hypersensitivity to cephalosporins (unlikely to be an issue in neonates). In renal impairment, the excretion of amoxicillin will be delayed. In infants with severe renal impairment, it may be necessary to reduce the total daily dose.
Drug Interactions	IV: Aminoglycosides, including gentamicin, should not be mixed with amoxicillin when both drugs are given parenterally as inactivation of the aminoglycoside occurs. Ensure line is adequately flushed between antibiotics. PO: No significant drug-drug interaction found for neonates on oral amoxicillin.
Adverse Reactions	Common: Diarrhoea, skin rash (erythematous maculopapular), phlebitis at the injection site, superinfection with resistant organisms during prolonged therapy Uncommon/rare: Neurotoxicity, electrolyte disturbances e.g. hypernatraemia due to the sodium content (3.3 mmol per gram in Amoxil IV and 2.6 mmol per gram in Fisamox IV), erythema multiforme, exfoliative skin lesions, *C. difficile* diarrhoea, pancytopenia, raised liver enzymes. Amoxicillin may result in a false positive for glucose in the urine due to excessive amounts of urinary amoxicillin.
Compatibility	Fluids: Sodium chloride 0.9%, sterile water for injection Y site: No information[9]
Incompatibility	Fluids: Glucose and glucose-containing solutions, fat emulsions Y site: Aminoglycosides, ciprofloxacin, imipenem-cilastatin, midazolam, potassium chloride, sodium bicarbonate[9]
Stability	IV: The reconstituted solution should be administered immediately; discard unused portion of the reconstituted solution. PO: The medication mixed with milk should be administered immediately.
Storage	IV: Store below 25°C. Protect from light. PO: Store unreconstituted powder for oral suspension at 20–25 degrees Celsius. Reconstituted suspension is stable for 14 days at room temperature or if refrigerated. Refrigeration is preferred.
Special Comments	Clearance is primarily by the renal route. Clearance increases with increasing gestational age and postmenstrual age. Serum half-life is longer in premature infants and infants younger than 7 days.
Evidence summary	Refer to full version.
References	Refer to full version.

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