amoxicillin/clavulanate
(a-mox-i-sill-klav-yoo-lan-ate)
Antibiotics, Augmentin ES, Augmentin XR, Clavulin

Classification
Therapeutic: anti-infection
Pharmacologic: aminopenicillins/beta-lactamase inhibitors

Pregnancy Category B

Indications
Treatment of a variety of infections including: Skin and skin structure infections, Otitis media, Sinusitis, Respiratory tract infections, Genitourinary tract infections.

Action

Pharmacokinetics
Absorption: Well absorbed from the duodenum (75–90%). More resistant to acid inactivation than other penicillins.
Distribution: Diffuses readily into most body tissues and fluids. Does not readily enter brain/CSF; CSF penetration is q in the presence of inflamed meninges. Crosses the placenta and enters breast milk in small amounts.
Metabolism and Excretion: 70% excreted unchanged in the urine; 30% metabolized by the liver.
Half-life: 1–1.3 hr.

TIME/ACTION PROFILE (peak blood levels)

<table>
<thead>
<tr>
<th>ROUTE</th>
<th>ONSET</th>
<th>PEAK</th>
<th>DURATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>PO</td>
<td>30 min</td>
<td>1–2 hr</td>
<td>8–12 hr</td>
</tr>
</tbody>
</table>

Contraindications/Precautions
Contraindicated in: Hypersensitivity to penicillins or clavulanate, Suspension and chewable tablets contain aspartame and should be avoided in phenylketonurics; History of amoxicillin/clavulanate-associated hepatitis; Amoxicillin/clavulanate discontinuation due to rash; Concurrent rifampin, ketoconazole, and H2 blockers.

Use Cautiously in: Severe renal insufficiency (dose adjustment recommended); Hemodialysis patients; Pregnancy.

Adverse Reactions/Side Effects
CNS: SEIZURES (high doses), SEIZURES (high doses), SEIZURES (high doses).
GI: PSEUDOMEMBRANOUS COLITIS, diarrhea, hepatic dysfunction, nausea, vomiting.
GU: vaginal candidiasis.
Derm: rash, urticaria.
Hemat: blood dyscrasias.
Misc: allergic reactions including ANAPHYLAXIS and SERUM SICKNESS, superinfection.

Interactions
Drug-Drug: Probenecid p renal excretion and q blood levels of amoxicillin—therapy may be combined for this purpose. May q the effect of warfarin. Concurrent allopurinol therapy q risk of rash. May p the effectiveness of hormonal contraceptives.

Drug-Food: Clavulanate absorption is p by a high fat meal.

Route/Dosage
Most Infections (Dosing based on amoxicillin component)

PO (Adults and Children ≥40 kg): 250 mg q 8 hr or 500 mg q 12 hr.

Serious Infections and Respiratory Tract Infections
PO (Adults and Children ≥40 kg): 875 mg q 12 hr or 500 mg q 8 hr, acute bacte-
rial sinusitis—2000 mg q 12 hr for 10 days as an extended-release (ER) product. Community-acquired pneumonia—2000 mg every 12 hr for 7–10 days as ex-
tended-release (ER) product.

Recurrent/persistent acute otitis media due to Multidrug-resis-
tant Streptococcus pneumoniae, H. influenzae, or M. catarrhalis
PO (Children ≥40 kg): 80–90 mg/kg/day in divided doses q 12 hr for 10 days (an ER formulation only).

Renal Impairment
PO (Adults): CCr 10–30 mL/min—250–500 mg q 12 hr (do not use 875 mg tab-
lets). CCr 5–10 mL/min—250–500 mg q 24 hr.

Miscellaneous
Uncommon = Discontinued.
Otitis Media, Sinusitis, Lower Respiratory Tract Infections, Serious Infections

PO (Children ≤ 3 mo): 200 mg/5 mL or 400 mg/5 mL suspension — 45 mg/kg/day divided q 12 hr; 125 mg/5 mL or 250 mg/5 mL suspension — 40 mg/kg/day divided q 12 hr.

Less Serious Infections

PO (Children ≤ 3 mo): 200 mg/5 mL or 400 mg/5 mL suspension — 25 mg/kg/day divided q 12 hr or 20 mg/kg/day divided q 8 h.

PO (Children ≤ 3 mo): 15 mg/kg q 12 hr (125 mg/mL suspension recommended).

NURSING IMPLICATIONS

Assessment

- Assess for infection (vital signs; appearance of wound, sputum, urine, and stool; WBC) at beginning of and throughout therapy.
- Obtain a history before initiating therapy to determine previous use of and reactions to penicillins or cephalosporins. Persons with a negative history of penicillin sensitivity may still have an allergic response.
- Observe for signs and symptoms of anaphylaxis (rash, pruritus, laryngeal edema, wheezing). Notify health care professional immediately if these occur.
- Obtain specimens for culture and sensitivity prior to therapy. First dose may be given before receiving results.

Lab Test Considerations:

- May cause increased serum alkaline phosphatase, LDH, AST, and ALT concentrations. Elderly men and patients receiving prolonged treatment are at risk for hepatic dysfunction.
- May cause false-positive direct Coombs’ test result.

Potential Nursing Diagnoses

- Risk for infection (Indications) (Side Effects)
- Noncompliance (Patient/Family Teaching)

Implementation

- PO: Administer around the clock. Administer at the start of a meal to enhance absorption and to decrease GI side effects. Do not administer with high-fat meals; clavulanate absorption is decreased. XR tablet is scored and can be broken for ease of administration. Capsule contents may be emptied and swallowed with liquids. Chewable tablets should be crushed or chewed before swallowing with liquids. Make oral suspensions before administering. Refrigerated reconstituted suspension should be discarded after 10 days.
- PO: 250 mg tablets are not bioequivalent to one 500 mg tablet. 250 mg tablets and 250 mg chewable tablets are also not interchangeable. 500 mg tablets are not interchangeable with one 1000 mg SR tablet; amounts of clavulanic acid and durations of action are different. Augmentin ES 600 (600 mg/5 mL) does not contain the same amount of clavulanic acid as any of the other Augmentin suspensions. Suspensions are not inter interchangeable.
- PO: Do not administer 250 mg chewable tablets to children < 40 kg due to clavulanic content. Children ≤ 2 mos should receive the 125 mg/5 mL oral solution.

Patient/Family Teaching

- Instruct patients to take medication around the clock and to finish the drug completely as directed, even if feeling better. Advise patients that sharing of this medication may be dangerous.
- Teach parents or caregivers to calculate and measure doses accurately. Reinforce importance of using measuring device supplied by pharmacy or with product, not household items.
- Advise patient to report the signs of superinfection (furry overgrowth on the tongue, vaginal itching or discharge, loose or foul-smelling stools) and allergy.
- Instruct patient to notify health care professional immediately if diarrhea, abdominal cramping, fever, or bloody stools occur and not to treat with antidiarrheals without consulting health care professionals.
- Instruct the patient to notify health care professional if symptoms do not improve or if nausea or diarrhea persists when drug is administered with food.
- Instruct female patients taking oral contraceptives to use an alternate or additional method of contraception during therapy and until next menstrual period; may decrease effectiveness of hormonal contraceptives.

Evaluation/Desired Outcomes

- Resolution of the signs and symptoms of infection. Length of time for complete resolution depends on the organism and site of infection.

Why was this drug prescribed for your patient?