AUGMENT®

Amoxicillin and Clavulanic Acid Film Coated Tablet,
Powder for Suspension and Powder for Injection

DESCRIPTION

Augment® is a combined preparation of Amoxicillin and Clavulanic Acid. Amoxicillin is a semisynthetic antibiotic with a broad spectrum of bactericidal activity against many gram-positive and gram-negative microorganisms. Amoxicillin is, however, susceptible to degradation by β-lactamases, and therefore, the spectrum of activity does not include organisms which produce these enzymes. Clavulanic Acid is a β-lactam, structurally related to the penicillins, which possesses the ability to inactivate a wide range of β-lactamase enzymes commonly found in microorganisms resistant to Penicillins and Cephalosporins. In particular, it has good activity against the clinically important plasmid-mediated β-lactamases frequently responsible for transferred drug resistance. The formulation of Amoxicillin and Clavulanic acid protects Amoxicillin from degradation by β-lactamase enzymes and effectively extends the antibiotic spectrum of Amoxicillin to include many bacteria normally resistant to Amoxicillin and other β-lactam antibiotics. Thus, this combination possesses the distinctive properties of a broad-spectrum antibiotic and a β-lactamase inhibitor.

INDICATIONS

- Lower Respiratory Tract Infections – caused by β-lactamase–producing strains of *H. influenzae* and *M. catarrhalis.*
- Otitis Media – caused by β-lactamase–producing strains of *H. influenzae* and *M. catarrhalis.*
- Sinusitis – caused by β-lactamase–producing strains of *H. influenzae* and *M. catarrhalis.*
- Skin and Skin Structure Infections – caused by β-lactamase–producing strains of *S. aureus, E. coli,* and *Klebsiella spp.*
- Urinary Tract Infections – caused by β-lactamase–producing strains of *E. coli, Klebsiella spp.* and *Enterobacter spp.*

DOSAGE AND ADMINISTRATION OF ORAL AUGMENT PREPARATION

Neonates and infants aged < 12 weeks (< 3 months): Due to incompletely developed renal function affecting elimination of Amoxicillin in this age group, the recommended dose of this combination is 30 mg/kg/day divided every 12h, based on the Amoxicillin component. Clavulanate elimination is unaltered in this age group.

Patients aged 12 weeks (3 months) and older:

Infections	Dosing Regimen	
	every 12h	every 8h
Otitis Media, Sinusitis, Lower Respiratory Tract Infections, and more severe infections	45 mg/kg/day every12h	40 mg/kg/day every 8h
Less severe infections	25 mg/kg/day every 12h	20 mg/kg/day every 8h

Pediatrics patients weighting 40 kg and more and the adult patients: The usual adult dose is one 500 mg tablet every 12 hours or one 250 mg tablet every 8 hours. For more severe infections and infections of the respiratory tract, the dose should be one 875 mg tablet every 12 hours or one 500 mg tablet every 8 hours.

DOSAGE AND ADMINISTRATION OF AUGMENT IV INJECTION

Augment 1.2 IV injection can be reconstituted by dissolving the powder in 20 ml Water for Injection USP.

Augment 1.2 IV injection should not be reconstituted or mixed with: Dextrose solution, Sodium Bicarbonate solution for injection, Protein Hydrolysates or other Proteinaceous fluids, blood or plasma, Intravenous lipids. However, the reconstituted solution may be injected into the drip tubing of infusion fluids containing glucose, bicarbonate and dextran over a period of 3-4 minutes.

Administration

Note: Augment 1.2 IV Injection is not suitable for intramuscular or subcutaneous administration. The reconstituted vial can be administered intravenously by injection (over 2 minutes) or slow intravenous infusion (30 minutes). The contents of the vial must be used within 20 minutes and thereafter any unused material should be discarded.

Dosage Guideline

Adults and children over 12 years : Usually 1.2 g eight hourly. In more serious infections, increase frequency to six-hourly intervals.

Children 3 months-12 years : Usually 30 mg/kg eight hourly. In more serious infections, increase frequency to six-hourly intervals.

Children 0-3 months : 30 mg/kg every 12 hours in premature infants and in full term infants during the perinatal period, increasing to eight hours thereafter.

Note: Each 30 mg of this combination contains 25 mg amoxicillin and 5 mg Clavulanate.

CONTRAINDICATIONS

- Allergic reactions to any Penicillin
- In patients with a previous history of Cholestatic Jaundice/Hepatic Dysfunction

SIDE EFFECTS

- Diarrhea/loose stools
- Nausea and vomiting
- Skin rashes and Urticaria
- Mucocutaneous candidiasis

PRECAUTION AND WARNING

While this combination possesses the characteristic low toxicity of the Penicillin group of antibiotics, periodic assessment of organ system functions, including renal, hepatic, and hematopoietic function, is advisable during prolonged therapy. Severe and occasional hypersensitivity can be occurred with this combination. Pseudomembranous colitis has been reported with nearly all antibacterial agents, including this combination, and has ranged in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

USE IN PREGNANCY AND LACTATION

Pregnancy category B. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Ampicillin-class antibiotics are excreted in the milk; therefore, caution should be exercised when this combination is administered to a nursing woman.

PHARMACEUTICAL PRECAUTIONS

For Tablet:

Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of reach of children.

For Suspension:

Do not store above 25 °C temperature. Keep away from light and wet place. Reconstituted suspension should be kept tightly closed and to be consumed within 7 days of preparation while stored in a refrigerator (2-8 °C) temperature.

For IV Injection:

Do not store dry powder above 25° C. Keep away from light and wet place. Reconstituted injection should be used within 20 minutes. Do not freeze the reconstituted solution.

PACKAGING

Augment®375 Tablet : Box containing 3 strips of 6 tablets each. Each Film Coated Tablet contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 250 mg and Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 125 mg.

Augment®625 Tablet : Box containing 3 strips of 6 tablets each. Each Film Coated Tablet contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 500 mg and Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 125 mg.

Augment®1g Tablet : Box containing 2 strips of 6 tablets each. Each Film Coated Tablet contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 875 mg and Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 125 mg.

Augment® Suspension : Bottle containing powder for preparation of 100 mL suspension. After reconstitution, each 5 mL contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 125 mg and Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 31.25 mg.

Augment® Injection : Each combipack contains a vial of Co-Amoxiclav for Injection BP consisting of Amoxicillin Sodium equivalent to Amoxicillin 1 g and Potassium Clavulanate BP equivalent to Clavulanic Acid 200 mg and 2 ampoules of Water for Injection USP 10 mL.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
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