

Drug Profile: Augmentin (Amoxicillin / Clavulanate Potassium)

1. Essential Information (Must-Have)

Field	Data	Context / Why Needed
Drug Name	Augmentin	Brand name for the combination antibiotic.
Active Ingredients	Amoxicillin (as trihydrate) and Clavulanate Potassium	Identifies the specific active pharmaceutical ingredients.
Chemical Formulas	<ul style="list-style-type: none">Amoxicillin: $C_{16}H_{19}N_3O_5S$Clavulanate Potassium: $C_8H_8KNO_5$	Defines the precise chemical composition of each component.
Molecular Weights	Amoxicillin: 365.4 g/mol Clavulanate Potassium: 237.25 g/mol	Essential for formulation, dosing, and pharmacological calculations.

Mechanism of Action	Combination Beta-Lactam Antibiotic & Beta-Lactamase Inhibitor	Amoxicillin inhibits bacterial cell wall synthesis. Clavulanic acid irreversibly binds to and inactivates beta-lactamase enzymes produced by bacteria, preventing them from breaking down the amoxicillin.
Therapeutic Class	Penicillin-class Antibacterial	Categorizes the drug by its chemical structure and therapeutic use.
Indications	Treatment of infections caused by susceptible beta-lactamase-producing isolates in conditions such as: Lower Respiratory Tract Infections, Otitis Media, Sinusitis, Skin and Skin Structure Infections , and Urinary Tract Infections .	Defines the specific medical conditions the drug is FDA-approved to treat.

2. Regulatory Information

Field	Data
FDA Approval Status	Approved
FDA Approval Date	August 6, 1984 (Original NDA 050564)

EMA Approval Status	Approved (Authorized across EU member states)
EMA Approval Date	<i>Varies by member state</i> ; harmonized reviews completed in 2009 and 2015 .
Patent Expiry (US)	Expired . The key patents have expired, allowing for generic competition.

3. Commercial & Market Data (Nice to Have)

Field	Data	Notes
CAS Numbers	Amoxicillin: 26787-78-0 Clavulanate Potassium: 61177-45-5	Unique numerical identifiers for each chemical substance.
Brand Names	Augmentin, Augmentin ES-600, Augmentin XR (some formulations discontinued)	Various brand names for different formulations and strengths.
Clinical Trial Data	Numerous clinical trials over decades have established efficacy. For example, comparative studies have shown Augmentin's superior clinical and bacteriological efficacy against beta-lactamase-producing strains compared to amoxicillin alone in conditions like acute otitis media and sinusitis.	

Market Size	The global amoxicillin/clavulanate market is valued at approximately \$4.5 Billion (USD) annually as of 2024.	A widely prescribed, essential medicine globally.
Key Competitors	Generic Amoxicillin/Clavulanate , Azithromycin (Zithromax), Cefdinir (Omnicef), Doxycycline , Levofloxacin .	Competes with other broad-spectrum antibiotics and generic versions.
Manufacturer	Originally developed by Beecham Pharmaceuticals (now part of GlaxoSmithKline). Multiple generic manufacturers now exist.	The originator company.