

# 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"><li>• Amoxicillin: C<sub>16</sub>H<sub>19</sub>N<sub>3</sub>O<sub>5</sub>S</li><li>• Clavulanate Potassium: C<sub>8</sub>H<sub>8</sub>KNO<sub>5</sub></li></ul>	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.

<b>Mechanism of Action</b>	<b>Combination Beta-Lactam Antibiotic &amp; Beta-Lactamase Inhibitor</b>	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.
<b>Therapeutic Class</b>	<b>Penicillin-class Antibacterial</b>	Categorizes the drug by its chemical structure and therapeutic use.
<b>Indications</b>	Treatment of infections caused by susceptible beta-lactamase-producing isolates in conditions such as: <b>Lower Respiratory Tract Infections, Otitis Media, Sinusitis, Skin and Skin Structure Infections, and Urinary Tract Infections.</b>	Defines the specific medical conditions the drug is FDA-approved to treat.

## 2. Regulatory Information

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

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

### 3. Commercial & Market Data (Nice to Have)

Field	Data	Notes
<b>CAS Numbers</b>	<b>Amoxicillin:</b> 26787-78-0  <b>Clavulanate Potassium:</b> 61177-45-5	Unique numerical identifiers for each chemical substance.
<b>Brand Names</b>	<b>Augmentin, Augmentin ES-600, Augmentin XR</b> (some formulations discontinued)	Various brand names for different formulations and strengths.
<b>Clinical Trial Data</b>	Numerous clinical trials over decades have established efficacy. For example, <b>comparative studies</b> 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.	

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