PrAMOXIcillin Sodium and Potassium CLAVulanate for INJECTION

PrAmoxicillin Sodium and Potassium Clavulanate for Injection is indicated for the treatment of the following infections in adults and children:[1]

- Acute exacerbations of chronic bronchitis (adequately diagnosed)
- Community-acquired pneumonia
- Cystitis
- Pyelonephritis
- Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis
- Intra-abdominal infections

Prophylaxis against infections associated with major surgical procedures in adults, such as those involving the:

- Gastrointestinal tract
- Pelvic cavity
- Head and neck
- Biliary tract surgery

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Amoxicillin Sodium and Potassium Clavulanate for Injection and other antibacterial drugs, Amoxicillin Sodium and Potassium Clavulanate for Injection should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology data, susceptibility patterns, and local official antibiotic prescribing guidelines may contribute to the empiric selection of therapy.[1]

PrSandoz® Amoxi-Clav Tablet

PrAMOXIcillin Sodium and Potassium CLAVulanate for INJECTION

Pharmacokinetics (PK)[1]

What is the IV PK data?*

Dose administered	Dose	AUC (h.mg/l)	Mean peak serum concentration (µg/ml)	Urinary recovery (%, 0 to 6h)
	AMX			
AMX/CLA 500 mg/100 mg†	500 mg	25.5	32.2	66.5
AMX/CLA 1000 mg/200 mg†	1000 mg	76.3	105.4	77.4
AMX/CLA 2000 mg/200 mg‡	2000 mg	119	108	74.7
	CLA			
AMX/CLA 500 mg/100 mg†	100 mg	9.2	10.5	46.0
AMX/CLA 1000 mg/200 mg†	200 mg	27.9	28.5	63.8
AMX/CLA 2000 mg/200 mg‡	200 mg	18.2	13.9	51.4

Adapted from Amoxicillin Sodium and Potassium Clavulanate for Injection Product Monograph

AUC: area under the curve ± SD; SD: standard deviation; AMX: amoxicillin;
CLA: clavulanic acid
* Clinical significance has not been established.
† Given as bolus intravenous injection.
‡ Given as intravenous infusion over 30 min.

Pr AMOXIcillin Sodium and Potassium CLAVulanate for INJECTION

Pharmacokinetics (PK)[2]

What is the tablet PK data?*

Dose administered	Dose	AUC (h.mcg/l) ± SD	C_{max} (µg/ml)	Urinary recovery (%, 0 to 6h)
	AMX			
AMX/CLA 250 mg tablets	250	11.39 ± 1.60	4.45 ± 0.91	63.5
AMX/CLA 500 mg tablets	500	20.15 ± 3.31	7.66 ± 1.65	78.3
	CLA			
AMX/CLA 250 mg tablets	250	4.73 ± 1.67	2.27 ± 0.76	26.5
AMX/CLA 500 mg tablets	500	5.24 ± 1.63	2.33 ± 0.73	26.6

Adapted from Amoxi-Clav Tablet Product Monograph

Sandoz Amoxi-Clav Tablet (amoxicillin and clavulanate potassium tablets) is indicated for the treatment of the following infections when caused by Sandoz Amoxi-Clav Tablet susceptible strains of the designated bacteria:†

- Sinusitis when caused by β-lactamase-producing strains of *H. influenzae* or *Moraxella (Branhamella) catarrhalis*.
- Otitis Media when caused by β-lactamase-producing strains of *H. influenzae* or *Moraxella (Branhamella) catarrhalis*.
- Lower Respiratory Tract Infections when caused by β-lactamase-producing strains of *H. influenzae, K. pneumoniae, S. aureus* or *Moraxella (Branhamella) catarrhalis*.
- Skin and Soft Tissue Infections when caused by β-lactamase-producing strains of *S. aureus*.
- Urinary Tract Infections when caused by β-lactamase-producing strains of *E. coli*.

* Clinical significance has not been established.
† While Sandoz Amoxi-Clav Tablet is indicated only for the conditions listed above, infections caused by ampicillin (amoxicillin)-susceptible organisms are also amenable to Sandoz Amoxi-Clav Tablet treatment due to its amoxicillin content.

Dosing Recommendations for IV[1]

The daily dose of Amoxicillin Sodium and Potassium Clavulanate for Injection is determined based on the indication, severity and site of the infection, susceptibility of the pathogen(s) to Amoxicillin Sodium and Potassium Clavulanate for Injection and renal function. In children, it is also determined by age and body weight.

5:1 ratio†	10:1 ratio†
(500 mg/100 mg and 1000 mg/200 mg)	(2000 mg/200 mg)
Adults and Children ≥40 kg	
• 1000 mg/200 mg every 8 hours	• Usually 2000 mg/200 mg every 12 hours • For very severe infections, the dose may be increased to a maximum of 2000/200 mg every 8 hours
Children <40 kg	
Aged ≥3 months	
• 25 mg/5 mg/kg every 8 hours	• 50 mg/5 mg/kg every 8 hours
Aged less than 3 months or weighing <4 kg	
• 25 mg/5 mg/kg every 12 hours	• 50 mg/5 mg/kg every 12 hours

Adapted from Amoxicillin Sodium and Potassium Clavulanate for Injection Product Monograph

† Doses are expressed throughout in terms of Amoxicillin/clavulanic acid content.

Please consult the Product Monograph for complete dosage and administration instructions.

The duration of therapy should be determined by the response of the patient. Some infections (e.g. osteomyelitis) require longer periods of treatment. Treatment should not be extended beyond 14 days without review.

Local therapeutic guidelines should be considered on appropriate dosing frequencies for amoxicillin/clavulanic acid.

Pr AMOXIcillin Sodium and Potassium CLAVulanate for INJECTION

Dosing Recommendations for IV[1]

Dose adjustment in renal impairment

Dosing adjustments are based on the maximum recommended level of Amoxicillin.

- No dosage change is required for mild renal impairment (CrCl >30 mL/min).
- For moderate renal impairment (CrCl 10-30 mL/min), initial dose of 1000 mg/200 mg followed by 500 mg/100 mg every 12 hours for adults and children ≥40 kg, and 25 mg/5 mg/kg every 12 hours for children <40 kg.
- For severe renal impairment (CrCl <10 mL/min), initial dose of 1000 mg/200 mg followed by 500 mg/100 mg every 24 hours for adults and children ≥40 kg, and 25 mg/5 mg/kg every 24 hours for children <40 kg.
- For hemodialysis, initial dose of 1000 mg/200 mg followed by 500 mg/100 mg 24 hourly + a dose of 500 mg/100 mg at the end of dialysis for adults and children ≥40 kg, and 25 mg/5 mg/kg every 24 hours + a dose of 12.5/2.5 mg/kg at the end of dialysis for children <40 kg.†

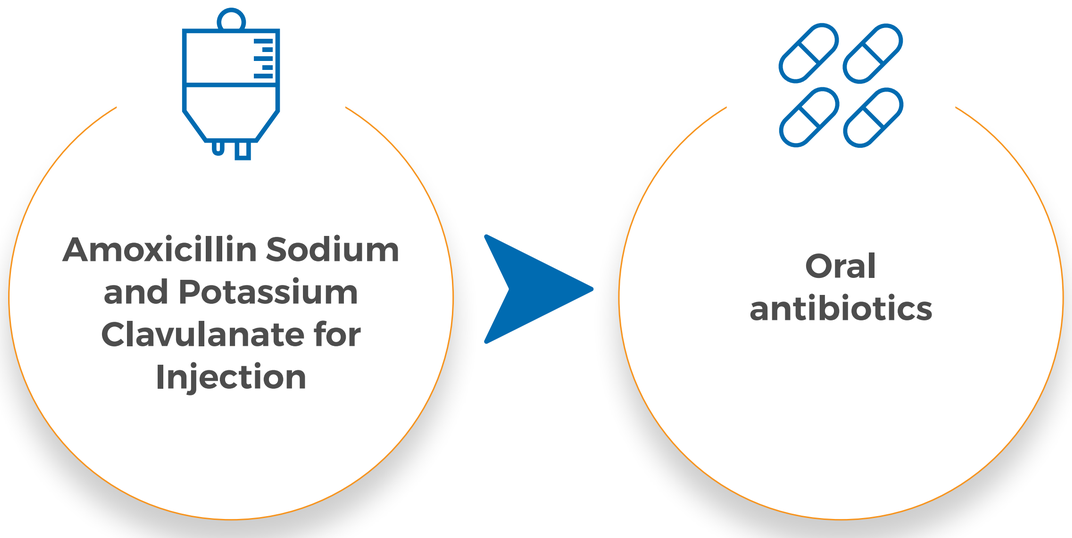
CrCl: creatinine clearance
† As serum concentrations of both Amoxicillin and clavulanic acid are decreased.

Administration

Amoxicillin Sodium and Potassium Clavulanate for Injection is for administration by IV route after reconstitution and is not suitable for intramuscular administration.

From IV to oral

Treatment with Amoxicillin Sodium and Potassium Clavulanate for Injection may be initiated and completed with an appropriate oral presentation as considered appropriate for the individual patient.



PrAMOXIcillin Sodium and Potassium CLAVulanate for INJECTION

Dosing Recommendations for tablet[2†]

Adults	
Mild to moderate infections	• 1 tablet (500 mg)/12 hours
Severe infections (including chronic and recurrent UTI and LRTI)	• 1 tablet (875 mg)/12 hours or • 1 tablet (500 mg)/8 hours

Adapted from Amoxi-Clav Tablet Product Monograph

Please consult the Product Monograph for complete dosage and administration instructions.

The normal duration of treatment is 7 to 10 days. However, in general, treatment should be continued for a minimum of 48 to 72 hours beyond the time that the patient becomes asymptomatic or evidence of bacterial eradication has been obtained. It is recommended that there be at least 10 days treatment for any infection caused by β-hemolytic streptococci to prevent the occurrence of acute rheumatic fever or glomerulonephritis.

UTI: urinary tract infections; LRTI: lower respiratory tract infections
† To minimize potential gastrointestinal intolerance, administer at the start of a meal.

Consider Amoxicillin Sodium and Potassium Clavulanate for Injection

Appearance	Strength	Format	UPC	DIN
	500 mg amoxicillin (as amoxicillin sodium) and 100 mg clavulanic acid (as clavulanate potassium)	Powder for Solution for Intravenous Injection – pack of 10 vials	0 57513 22063 0	02495910
	1000 mg amoxicillin (as amoxicillin sodium) and 200 mg clavulanic acid (as clavulanate potassium)	Powder for Solution for Intravenous Injection – pack of 10 vials	0 57513 22064 7	02495929
	2000 mg amoxicillin (as amoxicillin sodium) and 200 mg clavulanic acid (as clavulanate potassium)	Powder for Solution for Intravenous Injection – pack of 10 vials	0 57513 22062 3	02495937

> Sandoz is committed to antimicrobial stewardship

Sandoz, a global leader in bio-generic pharmaceuticals

- Committed to responsible and appropriate use of existing antibiotics.

PrAMOXIcillin Sodium and Potassium CLAVulanate for INJECTION

Consider Sandoz Amoxi-Clav Tablet

Appearance	Strength	Format	UPC	DIN
	500 mg amoxicillin (as trihydrate) and 125 mg clavulanic acid (as clavulanate potassium)	Bottle of 100 tablets	057513220319	02482576
	875 mg amoxicillin (as trihydrate) and 125 mg clavulanic acid (as clavulanate potassium)	Bottle of 100 tablets	057513220302	02482584

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[Pr]Amoxicillin Sodium and Potassium Clavulanate for Injection is also indicated for the treatment of the following infections in adults and children:

- Severe infections of the ear, nose and throat (such as mastoiditis, peritonsillar infections, epiglottitis, and sinusitis when accompanied by severe systemic signs and symptoms)
- Bone and joint infections, in particular osteomyelitis
- Female genital infections

Please consult the Amoxicillin Sodium and Potassium Clavulanate for Injection Product Monograph at https://www.sandoz.ca/sites/www.sandoz.ca/files/131-AmoxClav%20Inj%20PMe%2020200131.pdf for important information relating to:

- Contraindication in patients with hypersensitivity to this drug or to any ingredient in the formulation, a history of hypersensitivity to beta-lactams, and previous history of Amoxicillin/clavulanic acid-associated jaundice/hepatic dysfunction.
- The most serious warnings and precautions regarding serious and occasionally fatal hypersensitivity reactions.
- Other relevant warnings and precautions, such as severe cutaneous adverse reactions, cardiovascular, *clostridium difficile*-associated disease, hepatic events, convulsions, development of drug-resistant bacteria, increased INR, driving or operating machinery, monitoring and laboratory tests, patients with renal impairment, sodium and potassium content, pregnancy, breastfeeding.
- Conditions of clinical use, adverse reactions, drug interactions, and dosing information.

The Product Monograph is also available by calling 1-800-361-3062.

[Pr]AMOXIcillin Sodium and Potassium CLAVulanate for INJECTION

Please consult the Sandoz Amoxi-Clav Tablet Product Monograph at https://www.sandoz.ca/sites/www.sandoz.ca/files/Sandoz_Amoxi-Clav%20Tablet%20Product%20Monograph.pdf for important information relating to:

- Contraindication in patients with hypersensitivity to the penicillin or cephalosporin group of β-lactams, or to any ingredient contained in the preparation or component of the container, a previous history of Amoxicillin/clavulanic tablet-associated jaundice/hepatic dysfunction, and patients where infectious mononucleosis is either suspected or confirmed.
- Relevant warnings and precautions regarding serious and occasionally fatal hypersensitivity reactions, severe cutaneous adverse reactions, *clostridium difficile*-associated disease, development of drug-resistant bacteria, pregnancy, breastfeeding.
- Conditions of clinical use, adverse reactions, drug interactions, and dosing information.

The Product Monograph is also available by calling 1-800-361-3062.

References: 1. Amoxicillin Sodium and Potassium Clavulanate for Injection. Product Monograph. Sandoz Canada Inc. March 24, 2021.
2. Sandoz Amoxi-Clav Tablet (Amoxicillin and Clavulanate Potassium Tablet). Product Monograph. Sandoz Canada Inc. March 20, 2020.

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REVIEWED BY PAAB

PrSandoz® Amoxi-Clav Tablet