



Ampicillin and Sulbactam for Injection, USP

Piramal's Ampicillin and Sulbactam for Injection, USP is available through the wholesaler ordistributor of your choice

Wholesaler / Distributor Name	10 Vials in a carton: NDC - 66794-206-41 Ampicillin and Sulbactam for Injection, USP (1.5 grams per vial) Catalog numbers	10 Vials in a carton: NDC - 66794-207-41 Ampicillin and Sulbactam for Injection, USP (3 grams per vial) Catalog numbers	1 Bottle in a carton: NDC - 66794-208-15 Ampicillin and Sulbactam for Injection, USP (15 grams per bottle) Catalog numbers
AmerisourceBergen	10221529	10221610	10221620
Cardinal	5536560	5536578	5534417
McKesson	3949492	3949500	3949484
Morris & Dickson	630301	630319	630327

ABBREVIATED PRESCRIBING INFORMATION

PRODUCT NAME AND COMPOSITION: Ampicillin and Sulbactam for Injection, an injectable antibacterial combination consisting of the semi synthetic antibacterial Ampicillin sodium and the beta-lactamase inhibitor Sulbactam sodium for intravenous and intramuscular administration. Supplied in 1.5 grams vials (1 gram Ampicillin as the sodium salt plus 0.5 gram Sulbactam as the sodium salt) and 3 grams vials (2 grams Ampicillin as the sodium salt plus 1 gram Sulbactam as the sodium salt).

Please refer to Full Prescribing Information (FPI) before prescribing.

INDICATIONS: Treatment of infections due to susceptible strains of the designated microorganisms in the conditions listed in the FPI.

DOSAGE AND ADMINISTRATION: See FPI for full details. Ampicillin and Sulbactam for injection may be administered by either IV or IM routes. For intravenous administration, the dose can be given by slow intravenous injection over at least 10 to 15 minutes or can also be delivered in greater dilutions with 50 to 100 mL of a compatible diluent as an intravenous infusion over 15 to 30 minutes. Ampicillin and Sulbactam for injection may also be administered by deep intramuscular injection. The recommended adult dosage of Ampicillin and Sulbactam for injection is 1.5 grams (1 gram Ampicillin as the sodium salt plus 0.5 gram Sulbactam as the sodium salt) to 3 grams (2 grams Ampicillin as the sodium salt plus 1 gram Sulbactam as the sodium salt) every six hours. The total dose of Sulbactam should not exceed 4 grams per day. **Pediatric Patients** (1 year of age or older): The recommended daily dose is 300 mg per kg of body weight administered via intravenous infusion in equally divided doses every 6 hours. Pediatric patients weighing 40 kg or more should be dosed according to adult recommendations. **Patients with Impaired Renal Function:** The elimination kinetics of Ampicillin and Sulbactam are similarly affected, hence the ratio of one to the other will remain constant whatever the renal function. The dose of Ampicillin and Sulbactam for injection in such patients should be administered less frequently in accordance with the usual practice for Ampicillin.

CONTRAINDICATIONS: History of serious hypersensitivity reactions (e.g., anaphylaxis or Stevens-Johnson syndrome) to Ampicillin, Sulbactam or to other beta-lactam antibacterial drugs (e.g., penicillins and cephalosporins). History of cholestatic jaundice/hepatic dysfunction associated with Ampicillin and Sulbactam for injection.

COMMON SIDE EFFECTS: **Local:** Pain at IM injection site (16%), pain at IV injection site (3%), thrombophlebitis (3%), and phlebitis (1.2%). **Systemic:** Diarrhea (3%), rash (<2%). See FPI for a complete list.

WARNINGS AND PRECAUTIONS: To reduce the development of drug-resistant bacteria and maintain effectiveness of Ampicillin and Sulbactam for injection and other antibacterial drugs, Ampicillin and Sulbactam 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 and susceptibility patterns may contribute to the empiric selection of therapy. See FPI for full details. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. These reactions are more apt to occur in individuals with a history of penicillin hypersensitivity and/or hypersensitivity reactions to multiple allergens. Hepatic dysfunction, including hepatitis and cholestatic jaundice has been associated with the use of Ampicillin and Sulbactam for injection. Hepatic toxicity is usually reversible. Hepatic function should be monitored at regular intervals in patients with hepatic impairment. Ampicillin and Sulbactam for injection may cause severe skin reactions, such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), dermatitis exfoliative, erythema multiforme, and acute generalized exanthematous pustulosis (AGEP). If patients develop a skin rash they should be monitored closely and Ampicillin and Sulbactam for injection discontinued if lesions progress. *Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Ampicillin and Sulbactam for injection, and may range in severity from mild diarrhea to fatal colitis. See FPI for full details.

OVERDOSAGE: Neurological adverse reactions, including convulsions, may occur with the attainment of high cerebrospinal fluid (CSF) levels of beta-lactams. Ampicillin may be removed from circulation by hemodialysis. The molecular weight, degree of protein binding and pharmacokinetics profile of Sulbactam suggest that this compound may also be removed by hemodialysis.

For more information, please contact Piramal Customer Service at +1-800-414-1901 during business hours (8 a.m. EST to 5 p.m. EST) or e-mail at pcc.customerservice@piramal.com

- Full prescribing information of Ampicillin and Sulbactam for Injection, USP can be seen at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=85b35500-6aef-c24f-e053-2991aa0a2040>.
- Adverse events should be reported to Piramal Critical Care at <http://pcc-chex.force.com/SiteComplaintForm>.
- You are encouraged to report adverse events of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

“Saving and Improving Patients' Lives.”



Piramal Critical Care, Inc.

3950 Schelden Circle, Bethlehem, PA 18017, USA

Toll Free No.: +1-800-414-1901 www.piramalcriticalcare.com/us/



<https://www.linkedin.com/company/piramal-critical-care/>