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Ampicillin-Sulbactam

Updated: March 30, 2016.

OVERVIEW

The combination of ampicillin and sulbactam sodium combines a third generation aminopenicillin and a beta-lactamase inhibitor and is used to treat serious bacterial infections due to susceptible organisms. Given parenterally, ampicillin and sulbactam can cause mild transient aminotransferase elevations and has been linked to very rare instances of acute liver injury.

Background

The combination of ampicillin (am" pi sil' in) with sulbactam (sul bak' tam) is a broad spectrum, potent antibiotic which combines a third generation, aminopencillin with a beta lactamase inhibitor. This combination was approved for use in the United States in 1986. Current indications are for moderate-to-severe skin and skin structure, intra-abdominal and gynecological infections due to susceptible gram-positive and gram-negative bacteria, including beta-lactamase-producing strains of Staphylococcus aureus, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Bacteroides species, Enterobacter species, Neisseria meningitidis and gonorrhoeae, Moraxella catarrhalis and Acinetobacter calcoaceticus. The combination of ampicillin and sulbactam is available in a parenteral form generically and under the name Unasyn. The typical dose is 1.5 to 3 grams intramuscularly or intravenously every 6 hours for 7 to 14 days.

Hepatotoxicity

Parenteral therapy with ampicillin-sulbactam has been reported to cause transient low level elevations in serum aminotransferase levels in 5% to 10% of patients, but these resolve rapidly once the therapy is stopped, and similar rates of enzyme elevations are found with comparable agents. Clinically apparent liver injury due to ampicillin-sulbactam is very rare, instances published in individual case reports only. The reactions have been attributed to ampicillin rather than sulbactam and resemble the hepatic injury that occurs with ampicillin or amoxicillin alone. The liver injury is typically abrupt with short latency period and cholestatic features. The onset of hepatic injury may be accompanied by eosinophilia, arthralgias and skin rash, and occasionally with toxic epidermal necrolysis or Stevens-Johnson syndrome.

Likelihood score: C (probable cause of clinically apparent liver injury).

Mechanism of Injury

The cause of the liver injury associated with ampicillin use is probably hypersensitivity or allergy. Recurrence of hepatic injury has been reported after ampicillin induced liver injury with reexposure to ampicillin.

Outcome and Management

In the few cases that have been described, most patients have recovered although recovery has been slow in some cholestatic instances (2 to 6 months). Acute liver failure and vanishing bile duct syndrome have been reported with aminopenicillin induced liver injury, but not specifically with ampicillin-sulbactam. Corticosteroids have often been used to treat the allergic manifestations of penicillin related immunoallergic hepatitis; while corticosteroid therapy may improve fever and rash promptly, their efficacy in ameliorating the accompanying liver disease has not been shown. Instances of recurrence of liver injury with reexposure to aminopenicillins and recurrence with exposure to cephalosporins have been reported. Patients with aminopenicillin induced hepatitis should avoid reexposure to other penicillins and should take cephalosporins with caution.

References to the hepatotoxicity and safety of ampicillin-sulbactam are given in the Overview section on the aminopenicillins.

Drug Class: Antiinfective Agents, Aminopenicillins

Other Drugs in the Subclass, Aminopenicillns: Amoxicillin, Amoxicillin-Clavulanate, Ampicillin, Bacampicillin, Pivampicillin

PRODUCT INFORMATION

REPRESENTATIVE TRADE NAMES

Ampicillin-Sulbactam – Unasyn®

DRUG CLASS

Antiinfective Agents

COMPLETE LABELING

Product labeling at DailyMed, National Library of Medicine, NIH

CHEMICAL FORMULA AND STRUCTURE

DRUG	CAS REGISTRY NO	MOLECULAR FORMULA	STRUCTURE
Ampicillin-Sulbactam	94935-63-4	C16-H19-N3-O4.S C8-H11-N-O5-S