

[Skip to main content](#)

Augmentin XR (Amoxicillin Clavulanic Potassium)

??? ??????: 30 ?????2/????? 2017

The following are discussed in more detail in other sections of the labeling:

-]**WARNINGS AND PRECAUTIONS** Anaphylactic reactions [see
-]**WARNINGS AND PRECAUTIONS** Hepatic Dysfunction [see
-]**WARNINGS AND PRECAUTIONS** CDAD [see

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

-In clinical trials, 5,643 patients have been treated with AUGMENTIN XR. The most frequently reported adverse reactions which were suspected or probably drug related were diarrhea (15%), vaginal mycosis (3%) nausea (2%), and loose stools (2%). AUGMENTIN XR had a higher rate of diarrhea which required corrective therapy (4% versus 3% for AUGMENTIN XR and all comparators, respectively). Two percent of patients discontinued therapy because of drug-related adverse reactions.

Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following have been identified during postmarketing use of AUGMENTIN products, including AUGMENTIN XR. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These events have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal connection to AUGMENTIN.

Diarrhea, nausea, vomiting, indigestion, gastritis, stomatitis, glossitis, black "hairy" tongue, mucocutaneous candidiasis, enterocolitis, and **Gastrointestinal:** hemorrhagic/pseudo membranous colitis. Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment.

Skin rashes, pruritus, urticaria, angioedema, serum sickness-like reactions (urticaria or skin rash accompanied by arthritis, arthralgia, **Hypersensitivity Reactions:** myalgia, and frequently fever), erythema multiforme, Stevens-Johnson syndrome, acute generalized exanthematous pustulosis, hypersensitivity vasculitis, and an occasional case of exfoliative dermatitis (including toxic epidermal necrolysis) have been reported [see

A moderate rise in AST (SGOT) and/or ALT (SGPT) has been noted in patients treated with ampicillin-class antibiotics, but the significance of these findings is **Liver:**], increases in serum transaminases (AST and/or ALT), **CONTRAINDICATIONS** unknown. Hepatic dysfunction, including hepatitis and cholestatic jaundice, [see serum bilirubin, and/or alkaline phosphatase, has been reported with AUGMENTIN or AUGMENTIN XR. It has been reported more commonly in the elderly, in males, or in patients on prolonged treatment. The histologic findings on liver biopsy have consisted of predominantly cholestatic, hepatocellular, or mixed cholestatic hepatocellular changes. The onset of signs/symptoms of hepatic dysfunction may occur during or several weeks after therapy has been discontinued. The hepatic] **WARNINGS AND PRECAUTIONS** , **CONTRAINDICATIONS** dysfunction, which may be severe, is usually reversible. Deaths have been reported [see

] **OVERDOSAGE** Interstitial nephritis, hematuria, and crystalluria have been reported [see **Renal:**

Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis **Hemic and Lymphatic Systems:** have been reported during therapy with penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. There have been reports of increased prothrombin time in patients receiving AUGMENTIN and anticoagulant therapy concomitantly.

Agitation, anxiety, behavioral changes, confusion, convulsions, dizziness, headache, insomnia, and reversible hyperactivity have been **Central Nervous System:** reported rarely.

Tooth discoloration (brown, yellow, or gray staining) has been reported. Most reports occurred in pediatric patients. Discoloration was reduced or **Miscellaneous:** eliminated with brushing or dental cleaning in most cases.