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Biaxin, Biaxin XL (Clarithromycin)

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

The most frequent and common adverse reactions related to clarithromycin therapy for both adult and pediatric populations are abdominal pain, diarrhea, nausea, vomiting and dysgeusia. These adverse reactions are consistent with the known safety profile of macrolide antibiotics.

There was no significant difference in the incidence of these gastrointestinal adverse reactions during clinical trials between the patient population with or without preexisting mycobacterial infections.

Adverse Reactions Observed During Clinical Trials of Clarithromycin

The following adverse reactions were observed in clinical trials with clarithromycin at a rate greater than or equal to 1%:

Gastrointestinal Disorders

Diarrhea, vomiting, dyspepsia, nausea, abdominal pain

Hepatobiliary Disorders

Liver function test abnormal

Immune System Disorders

Anaphylactoid reaction

Infection and Infestations

Candidiasis

Nervous System Disorders

Dysgeusia, headache

Psychiatric Disorders Insomnia

Skin and Subcutaneous Tissue Disorders

Rash

Other Adverse Reactions Observed During Clinical Trials Of Clarithromycin

The following adverse reactions were observed in clinical trials with clarithromycin at a rate less than 1%:

Blood and Lymphatic System Disorders

Leukopenia, neutropenia, thrombocythemia, eosinophilia

Cardiac Disorders

Electrocardiogram QT prolonged, cardiac arrest, atrial fibrillation, extrasystoles, palpitations

Ear and Labyrinth Disorders

Vertigo, tinnitus, hearing impaired

Gastrointestinal Disorders

Stomatitis, glossitis, esophagitis, gastrooesophageal reflux disease, gastritis, proctalgia, abdominal distension, constipation, dry mouth, eructation, flatulence

General Disorders and Administration Site Conditions

Malaise, pyrexia, asthenia, chest pain, chills, fatigue

Hepatobiliary Disorders

Cholestasis, hepatitis

Immune System Disorders

Hypersensitivity

Infections and Infestations

Cellulitis, gastroenteritis, infection, vaginal infection

Investigations

Blood bilirubin increased, blood alkaline phosphatase increased, blood lactate dehydrogenase increased, albumin globulin ratio abnormal

Metabolism and Nutrition Disorders

Anorexia, decreased appetite

Musculoskeletal and Connective Tissue Disorders

Myalgia, muscle spasms, nuchal rigidity

Nervous System Disorders

Dizziness, tremor, loss of consciousness, dyskinesia, somnolence

Psychiatric Disorders

Anxiety, nervousness

Renal and Urinary Disorders

Blood creatinine increased, blood urea increased

Respiratory, Thoracic and Mediastinal Disorders

Asthma, epistaxis, pulmonary embolism

Skin and Subcutaneous Tissue Disorders

Urticaria, dermatitis bullous, pruritus, hyperhidrosis, rash maculo-papular

In the acute exacerbation of chronic bronchitis and acute maxillary sinusitis studies overall gastrointestinal adverse events were reported by a similar proportion of patients taking either BIAXIN tablets or BIAXIN XL tablets; however, patients taking BIAXIN XL tablets reported significantly less severe gastrointestinal symptoms compared to patients taking BIAXIN tablets. In addition, patients taking BIAXIN XL tablets had significantly fewer premature discontinuations for drug-related gastrointestinal or abnormal taste adverse events compared to BIAXIN tablets.

In community-acquired pneumonia studies conducted in adults comparing clarithromycin to erythromycin base or erythromycin stearate, there were fewer adverse events involving the digestive system in clarithromycin-treated patients compared to erythromycin-treated patients (13% vs 32%; $p < 0.01$). Twenty percent of erythromycin-treated patients discontinued therapy due to adverse events compared to 4% of clarithromycin-treated patients.

In two U.S. studies of acute otitis media comparing clarithromycin to amoxicillin/potassium clavulanate in pediatric patients, there were fewer adverse events involving the digestive system in clarithromycin-treated patients compared to amoxicillin/potassium clavulanate-treated patients (21% vs. 40%, $p < 0.001$). One-third as many clarithromycin-treated patients reported diarrhea as did amoxicillin/potassium clavulanate-treated patients.

Post-Marketing Experience

The following adverse reactions have been identified during post approval use of clarithromycin. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Blood and Lymphatic System Disorders

Thrombocytopenia, agranulocytosis

Cardiac Disorders

Torsades de pointes, ventricular tachycardia, ventricular arrhythmia

Ear and Labyrinth Disorders

Deafness was reported chiefly in elderly women and was usually reversible.

Gastrointestinal Disorders

Pancreatitis acute, tongue discoloration, tooth discoloration was reported and was usually reversible with professional cleaning upon discontinuation of the drug. There have been reports of BIAXIN XL tablets in the stool, many of which have occurred in patients with anatomic (including ileostomy or colostomy) or functional gastrointestinal disorders with shortened GI transit times. In several reports, tablet residues have occurred in the context of diarrhea. It is recommended that patients who experience tablet residue in the stool and no improvement in their condition should be switched to a different clarithromycin formulation (e.g. suspension) or another antibacterial drug.

Hepatobiliary Disorders

).**Hepatotoxicity**- **WARNINGS**Hepatic failure, jaundice hepatocellular. Adverse reactions related to hepatic dysfunction have been reported with clarithromycin (see

Immune System Disorders

Anaphylactic reaction

Infections and Infestations

Pseudomembranous colitis

Investigations

Prothrombin time prolonged, white blood cell count decreased, international normalized ratio increased. Abnormal urine color has been reported, associated with hepatic failure.

Metabolism and Nutrition Disorders

Hypoglycemia has been reported in patients taking oral hypoglycemic agents or insulin.

Musculoskeletal and Connective Tissue Disorders

Myopathy, rhabdomyolysis was reported and in some of the reports, clarithromycin was administered concomitantly with statins, fibrates, colchicine or allopurinol).**WARNINGS** and **CONTRAINDICATIONS**(see

Nervous System Disorders

Convulsion, ageusia, parosmia, anosmia, paraesthesia

Psychiatric Disorders

Psychotic disorder, confusional state, depersonalization, depression, disorientation, manic behavior, hallucination, abnormal behavior, abnormal dreams. These disorders usually resolve upon discontinuation of the drug.

There are no data on the effect of clarithromycin on the ability to drive or use machines. The potential for dizziness, vertigo, confusion and disorientation, which may occur with the medication, should be taken into account before patients drive or use machines.

Renal and Urinary Disorders

Nephritis interstitial, renal failure

Skin and Subcutaneous Tissue Disorders

Stevens-Johnson syndrome, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms (DRESS), Henoch-Schonlein purpura, acne

Vascular Disorders

Hemorrhage

There have been reports of colchicine toxicity with concomitant use of clarithromycin and colchicine, especially in the elderly, some of which occurred in patients

). **PRECAUTIONS**and **WARNINGS**with renal insufficiency. Deaths have been reported in some such patients (see