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Ciprofloxacin Hcl (Proquin XR)

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

Serious and Otherwise Important Adverse Reactions

The following serious and otherwise important adverse drug reactions are discussed in greater detail in other sections of labeling:

-]**WARNINGS AND PRECAUTIONS** Tendon Effects [see
-]**WARNINGS AND PRECAUTIONS** Hypersensitivity Reactions [see
-]**WARNINGS AND PRECAUTIONS** Other Serious and Sometimes Fatal Reactions [see
-]**WARNINGS AND PRECAUTIONS** Central Nervous System Effects [see
-]**WARNINGS AND PRECAUTIONS** -Associated Diarrhea [see*Clostridium difficile*
-]**WARNINGS AND PRECAUTIONS** Peripheral Neuropathy [see
-]**WARNINGS AND PRECAUTIONS** Photosensitivity/Phototoxicity [see
-]**WARNINGS AND PRECAUTIONS** Development of Drug Resistant Bacteria [see

Crystalluria and cylindruria have been reported with quinolones, including ciprofloxacin. Therefore, adequate hydration of patients receiving Proquin XR].**DOSAGE AND ADMINISTRATION**(ciprofloxacin hcl) should be maintained to prevent the formation of highly concentrated urine [see

Clinical Trial 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.

The data described below reflect exposure to Proquin XR (ciprofloxacin hcl) in 524 patients in one clinical trial. The population studied had a mean age of 39 years (approximately 93.4% of the population were < 65 years of age), 100% were female, 77% were Caucasian and 7.4% were Black. Patients received Proquin XR (ciprofloxacin hcl) 500 mg once daily for 3 days. Patients were followed for approximately 5 weeks after the end of study drug dosing.

Discontinuation of Proquin XR (ciprofloxacin hcl) occurred in 1.4% of patients. Each of the discontinuations were for a different adverse reactions. Refer to Table 1.

The most common adverse reactions (? 2%) were fungal infection, nasopharyngitis, headache, and micturition urgency.

Table 1: Adverse reactions (regardless of relationship to study drug) occurring in ? 1% of Proquin XR (ciprofloxacin hcl) -treated patients (500 mg once daily for 3 days) during the entire study period compared to ciprofloxacin-immediate release tablets (250 mg twice daily for 3 days)

-Ciprofloxacin immediate release tablets	Proquin XR	Adverse Reaction
2.4	1.4	Nausea
1.2	1.7	Abdominal pain
0.6	1.4	Suprapubic pain
9.8	10.8	Urinary tract infection
1.8	2.7	Fungal infection
2.9	1.4	Upper respiratory tract infection
1.6	1.7	Back pain
3.9	2.3	Headache
1.0	1.9	Micturition urgency
1.0	1.4	Urinary frequency
1.4	2.7	Nasopharyngitis
1.0	1.2	Pharyngitis

The incidence of adverse events (regardless of relationship to study drug) reported for at least 1% of patients treated with Proquin XR (ciprofloxacin hcl) during study drug treatment and up to 3 days after study drug was headache (1.5%).

Less common reactions, occurring at any time during the study in less than 1% of Proquin XR (ciprofloxacin hcl) -treated patients were:

- **Cardiac Disorders:** ventricular bigeminy.
- **Immune System Disorders:** hypersensitivity.
- **Gastrointestinal Disorders:** abdominal pain, nausea, diarrhea, dyspepsia, aggravated irritable bowel syndrome, lower abdominal pain, vomiting.
- **General Disorders:** suprapubic pain, fatigue, pain, rigors, tenderness.
- **Infections and Infestations:** urinary tract infection, fungal vaginosis, bacterial vaginitis, vaginal candidiasis, vaginal infection, vaginitis.
- **Investigations:** blood bilirubin increased, alanine aminotransferase increased, abdominal aortic bruit, aspartate aminotransferase increased, body temperature increased.
- **Musculoskeletal and Connective Tissue Disorders:** joint swelling, muscle spasms, night cramps.
- **Nervous System Disorders:** headache, dizziness, disturbance in attention, paresthesia.
- **Renal and Urinary Disorders:** micturition urgency, dysuria, urinary frequency, abnormal urine odor, hematuria.
- **Reproductive System and Breast Disorders:** female genital pruritus.
- **Respiratory, Thoracic, and Mediastinal Disorders:** dyspnea.
- **Skin/Subcutaneous Tissue Disorders:** rash, photosensitivity/ phototoxicity reaction, pruritus, urticaria.

Adverse Reactions Reported with Other Systemic Formulations of Ciprofloxacin

In addition, to the adverse reactions reported with Proquin XR (ciprofloxacin hcl) , the following adverse reactions have been reported during clinical trials and from worldwide post-marketing experience with other systemic formulations of ciprofloxacin (includes all dosages and indications).

Because these reactions have been reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or a causal relationship to drug exposure. Abnormal gait, achiness, acidosis, agitation, agranulocytosis, allergic reactions (ranging from urticaria to anaphylactic reactions)], amylase increase, anemia, angina pectoris, angioedema, anosmia, anxiety, arrhythmia, **WARNINGS AND PRECAUTIONS** and **CONTRAINDICATIONS**[see arthralgia, ataxia, atrial flutter, bleeding diathesis, blurred vision, bronchospasm, C. difficile associated diarrhea, candidiasis (cutaneous, oral), candiduria, cardiac **WARNINGS** murmur, cardiopulmonary arrest, cardiovascular collapse, cerebral thrombosis, chills, cholestatic jaundice, chromatopsia, confusion, convulsion [see], delirium, depression, diplopia, drowsiness, dysphagia, dyspnea, edema (conjunctivae, face, hands, laryngeal, lips, lower extremities, neck, **AND PRECAUTIONS** pulmonary), epistaxis, erythema multiforme, erythema nodosum, exfoliative dermatitis, fever, fixed eruptions, flushing, gastrointestinal bleeding, gout (flare up), grand mal convulsion, gynecomastia, hallucinations, hearing loss, hematuria, hemolytic anemia, hemoptysis, hemorrhagic cystitis, hepatic failure (including fatal], hepatic necrosis, hepatitis, hiccup, hyperesthesia, hyperpigmentation, hypertension, hypertonia, hypoesthesia, **WARNINGS AND PRECAUTIONS**cases) [see hypotension, ileus, insomnia, interstitial nephritis, intestinal perforation, jaundice, joint stiffness, lethargy, lightheadedness, lipase increase, lymphadenopathy, malaise, manic reaction, marrow depression, migraine, moniliasis (oral, gastrointestinal, vaginal), mouth dryness, myalgia, myasthenia, myasthenia gravis (possible exacerbation), myocardial infarction, myoclonus, nephritis, nightmares, nystagmus, oral ulceration, pain (arm, back, breast, chest, epigastric, eye, extremities, foot,], peripheral neuropathy, perspiration **WARNINGS AND PRECAUTIONS**jaw, neck, oral mucosa), palpitation, pancreatitis, pancytopenia, paranoia, paresthesia [see] pleural effusion, polyuria, postural **WARNINGS AND PRECAUTIONS**(increased), petechia, phlebitis, phobia, photosensitivity/phototoxicity reaction[see **WARNINGS** hypotension, prothrombin time prolongation, pseudomembranous colitis (the onset of symptoms may occur during or after antimicrobial treatment) [see], pulmonary embolism, purpura, renal calculi, renal failure, respiratory arrest, respiratory distress, restlessness, serum sickness-like reaction, **AND PRECAUTIONS**],**WARNINGS AND PRECAUTIONS** and **BOXED WARNING**Stevens-Johnson syndrome, sweating, syncope, tachycardia, taste loss, tendonitis, tendon rupture [see tinnitus, torsade de pointes, toxic epidermal necrolysis, toxic psychosis, tremor, twitching, unresponsiveness, urethral bleeding, urinary retention, urination (frequent), vaginal pruritus, vasculitis, ventricular ectopy, vesicles, visual acuity (decreased), visual disturbances (flashing lights, change in color perception, overbrightness of lights), weakness.

The following adverse laboratory changes, in alphabetical order, regardless of incidence or relationship to drug, have been reported in patients given ciprofloxacin (includes all formulations, all dosages, all drug-therapy durations, and all indications):

Decreases in blood glucose, BUN, hematocrit, hemoglobin, leukocyte counts, platelet counts, prothrombin time, serum albumin, serum potassium, total serum protein, uric acid.

Increases in alkaline phosphatase, ALT (SGPT), AST (SGOT), atypical lymphocyte counts, blood glucose, blood monocytes, BUN, cholesterol, eosinophils counts, LDH, platelet counts, prothrombin time, sedimentation rate, serum amylase, serum bilirubin, serum calcium, serum cholesterol, serum creatinine phosphokinase, serum creatinine, serum gamma-glutamyl transpeptidase (GGT), serum potassium, serum theophylline (in patients receiving theophylline concomitantly), serum triglycerides, uric acid.

Others: albuminuria, change in serum phenytoin, crystalluria, cylindruria, immature WBCs, leukocytosis, methemaglobinemia, pancytopenia.