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Zagam (Sparfloxacin)

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In clinical trials, most of the adverse events were mild to moderate in severity and transient in nature. During clinical investigations with the recommended dosage, 1585 patients received sparfloxacin and 1331 patients received a comparator. The discontinuation rate due to adverse events was 6.6% for sparfloxacin versus 5.6% for cefaclor, 14.8% for erythromycin, 8.9% for ciprofloxacin, 7.4% for ofloxacin, and 8.3% for clarithromycin.

The most frequently reported events (remotely, possibly, or probably drug related with an incidence of ? 1%) among sparfloxacin treated patients in the US phase 3 clinical trials with the recommended dosage were: photosensitivity reaction (7.9%), diarrhea (4.6%), nausea (4.3%), headache (4.2%), dyspepsia (2.3%), dizziness interval prolongation (1.3%), vomiting (1.3%), flatulence (1.1%), $_{c}$(2.0%), insomnia (1.9%), abdominal pain (1.8%), pruritus (1.8%), taste perversion (1.4%), and QT and vasodilatation (1.0%).

In US phase 3 clinical trials of shorter treatment duration than the recommended dosage, the most frequently reported events (incidence ? 1%, remotely, possibly, or probably drug related) were: headache (8.1%), nausea (7.6%), dizziness (3.8%), photosensitivity reaction (3.6%), pruritus (3.3%), diarrhea (3.2%), vaginal moniliasis (2.8%), abdominal pain (2.4%), asthenia (1.7%), dyspepsia (1.6%), somnolence (1.5%), dry mouth (1.4%), and rash (1.1%).

Additional possibly or probably related events that occurred in less than 1% of all patients enrolled in US phase 3 clinical trials are listed below:

fever, chest pain, generalized pain, allergic reaction, cellulitis, back pain, chills, face edema, malaise, accidental injury, anaphylactoid reaction,**BODY AS A WHOLE:** infection, mucous membrane disorder, neck pain, rheumatoid arthritis;

palpitation, electrocardiogram abnormal, hypertension, tachycardia, sinus bradycardia, PR interval shortened, angina pectoris, arrhythmia, **CARDIOVASCULAR:** atrial fibrillation, atrial flutter, complete AV block, first degree AV block, second degree AV block, cardiovascular disorder, hemorrhage, migraine, peripheral vascular disorder, supraventricular extrasystoles, ventricular extrasystoles, postural hypotension;

constipation, anorexia, gingivitis, oral moniliasis, stomatitis, tongue disorder, tooth disorder, gastroenteritis, increased appetite, mouth **GASTROINTESTINAL:** ulceration, flatulence, vomiting;

cyanosis, ecchymosis, lymphadenopathy; **HEMATOLOGIC:**

gout, peripheral edema, thirst; **METABOLISM:**

arthralgia, arthritis, joint disorder, myalgia; **MUSCULOSKELETAL:**

paresthesia, hypesthesia, nervousness, somnolence, abnormal dreams, dry mouth, depression, tremor, anxiety, confusion, **CENTRAL NERVOUS SYSTEM:** hallucinations, hyperesthesia, hyperkinesia, sleep disorder, hypokinesia, vertigo, abnormal gait, agitation, lightheadedness, emotional lability, euphoria, abnormal thinking, amnesia, twitching;

asthma, epistaxis, pneumonia, rhinitis, pharyngitis, bronchitis, hemoptysis, sinusitis, cough increased, dyspnea, laryngismus, lung disorder, pleural **RESPIRATORY:** disorder;

rash, maculopapular rash, dry skin, herpes simplex, sweating, urticaria, vesiculobullous rash, exfoliative dermatitis, acne, alopecia, **SKIN/HYPERSENSITIVITY:** angioedema, contact dermatitis, fungal dermatitis, furunculosis, pustular rash, skin discoloration, herpes zoster, petechial rash;

ear pain, amblyopia, photophobia, tinnitus, conjunctivitis, diplopia, abnormality of accommodation, blepharitis, ear disorder, eye pain, lacrimation**SPECIAL SENSES:** disorder, otitis media;

vaginitis, dysuria, breast pain, dysmenorrhea, hematuria, menorrhagia, nocturia, polyuria, urinary tract infection, kidney pain, leukorrhea, **UROGENITAL:** metrorrhagia, vulvovaginal disorder.

Laboratory Changes

In the US phase 3 clinical trials, with the recommended dosage, the most frequently (incidence ? 1%) reported changes in laboratory parameters listed as adverse events, regardless of relationship to drug, were: elevated ALT (SGPT) (2.0%), AST (SGOT) (2.3%), and white blood cells (1.1%).

Increases for the following laboratory tests were reported in less than 1% of all patients enrolled in clinical trials: alkaline phosphatase, serum amylase, aPTT, blood

urea nitrogen, calcium, creatinine, eosinophils, serum lipase, monocytes, neutrophils, total bilirubin, urine glucose, urine protein, urine red blood cells, and urine white blood cells.

Decreases for the following laboratory tests were reported in less than 1% of all patients enrolled in clinical trials: albumin, creatinine clearance, hematocrit, hemoglobin, lymphocytes, phosphorus, red blood cells, and sodium.

Increases and decreases for the following laboratory tests were reported in less than 1% of all patients in clinical trials: blood glucose, platelets, potassium, and white blood cells.

Postmarketing Adverse Events

The following are additional adverse events (regardless of relationship to drug) reported from worldwide postmarketing experience with sparfloxacin or other quinolones: acidosis, acute renal failure, agranulocytosis, albuminuria, anaphylactic shock, angioedema, anosmia, ataxia, bullous eruption, candiduria, cardiopulmonary arrest, cerebral thrombosis, convulsions, crystalluria, dysgeusia, dysphasia, ebrious feeling, embolism, erythema nodosum, exacerbation of myasthenia gravis, gastralgia, hemolytic anemia, hepatic failure, hepatic necrosis, hepatitis, hiccough, hyperpigmentation, interstitial nephritis, interstitial pneumonia, intestinal perforation, jaundice, laryngeal or pulmonary edema, manic reaction, numbness, nystagmus, painful oral mucosa, pancreatitis, pancytopenia, phobia, prolongation of prothrombin time, pseudomembranous colitis, Quincke's edema, renal calculi, rhabdomyolysis, sensory disturbance, Stevens-Johnson syndrome, squamous cell carcinoma, tendonitis, tendon rupture, tremor, thrombocytopenia, thrombocytopenia purpura, torsades de pointes, toxic epidermal necrolysis, toxic psychosis, urinary retention, uveitis, vaginal candidiasis, vasculitis.

Laboratory changes

elevation of serum triglycerides, serum cholesterol, blood glucose, serum potassium, decrease in WBC counts, RBC counts, hemoglobin level, hematocrit level, thrombocyte counts, elevation in GOT, GPT, ALP, LDH, ?-GTP, total bilirubin.