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Clinoril (Sulindac)

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

The following adverse reactions were reported in clinical trials or have been reported since the drug was marketed. The probability exists of a causal relationship between CLINORIL (sulindac) and these adverse reactions. The adverse reactions which have been observed in clinical trials encompass observations in 1,865 patients, including 232 observed for at least 48 weeks.

Incidence Greater Than 1%

Gastrointestinal

The most frequent types of adverse reactions occurring with CLINORIL (sulindac) are gastrointestinal; these include gastrointestinal pain (10%), dyspepsia***, nausea*** with or without vomiting, diarrhea***, constipation***, flatulence, anorexia and gastrointestinal cramps.

Dermatologic

Rash***, pruritus.

Central Nervous System

Dizziness***, headache***, nervousness.

Special Senses

Tinnitus.

Miscellaneous

).**WARNINGS** Edema (see

Incidence Less Than 1 in 100

Gastrointestinal

Gastritis, gastroenteritis or colitis. Peptic ulcer and gastrointestinal bleeding have been reported. GI perforation and intestinal strictures (diaphragms) have been reported rarely.

Liver function abnormalities; jaundice, sometimes with fever; cholestasis; hepatitis; hepatic failure.

There have been rare reports of sulindac metabolites in common bile duct “sludge” and in biliary calculi in patients with symptoms of cholecystitis who underwent a cholecystectomy.

).**PRECAUTIONS** Pancreatitis (see

Ageusia; glossitis.

Dermatologic

Stomatitis, sore or dry mucous membranes, alopecia, photosensitivity.

Erythema multiforme, toxic epidermal necrolysis, Stevens-Johnson syndrome, and exfoliative dermatitis have been reported.

Cardiovascular

Congestive heart failure, especially in patients with marginal cardiac function; palpitation; hypertension.

Hematologic

Thrombocytopenia; ecchymosis; purpura; leukopenia; agranulocytosis; neutropenia; bone marrow depression, including aplastic anemia; hemolytic anemia;).**PRECAUTIONS**increased prothrombin time in patients on oral anticoagulants (see

Genitourinary

Urine discoloration; dysuria; vaginal bleeding; hematuria; proteinuria; crystalluria; renal impairment, including renal failure; interstitial nephritis; nephrotic syndrome.

Renal calculi containing sulindac metabolites have been observed rarely.

Metabolic

Hyperkalemia.

Musculoskeletal

Muscle weakness.

Psychiatric

Depression; psychic disturbances including acute psychosis.

Nervous System

Vertigo; insomnia; somnolence; paresthesia; convulsions; syncope; aseptic meningitis (especially in patients with systemic lupus erythematosus (SLE) and mixed).**PRECAUTIONS**connective tissue disease, see

Special Senses

Blurred vision; visual disturbances; decreased hearing; metallic or bitter taste.

Respiratory

Epistaxis.

Hypersensitivity Reactions

Anaphylaxis; angioneurotic edema; urticaria; bronchial spasm; dyspnea.

Hypersensitivity vasculitis.

A potentially fatal apparent hypersensitivity syndrome has been reported. This syndrome may include constitutional symptoms (fever, chills, diaphoresis, flushing), cutaneous findings (rash or other dermatologic reactions - see above), conjunctivitis, involvement of major organs (changes in liver function including hepatic failure, jaundice, pancreatitis, pneumonitis with or without pleural effusion, leukopenia, leukocytosis, eosinophilia, disseminated intravascular coagulation, anemia, renal impairment, including renal failure), and other less specific findings (adenitis, arthralgia, arthritis, myalgia, fatigue, malaise, hypotension, chest pain, tachycardia).

Causal Relationship Unknown

A rare occurrence of fulminant necrotizing fasciitis, particularly in association with Group A ?-hemolytic streptococcus, has been described in persons treated with).**also PRECAUTIONS, General**non-steroidal anti-inflammatory agents, sometimes with fatal outcome (see

Other reactions have been reported in clinical trials or since the drug was marketed, but occurred under circumstances where a causal relationship could not be established. However, in these rarely reported events, that possibility cannot be excluded. Therefore, these observations are listed to serve as alerting information to physicians.

Cardiovascular

Arrhythmia.

Metabolic

Hyperglycemia.

Nervous System

Neuritis.

Special Senses

Disturbances of the retina and its vasculature.

Miscellaneous

Gynecomastia.

*** Incidence between 3% and 9%. Those reactions occurring in 1% to 3% of patients are not marked with an asterisk.