Skip to main content

Accutane (Isotretinoin)

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

Clinical Trials and Postmarketing Surveillance

The adverse reactions listed below reflect the experience from investigational studies of Accutane (isotretinoin) , and the postmarketing experience. The relationship of some of these events to Accutane (isotretinoin) therapy is unknown. Many of the side effects and adverse reactions seen in patients receiving Accutane (isotretinoin) are similar to those described in patients taking very high doses of vitamin A (dryness of the skin and mucous membranes, eg, of the lips, nasal passage, and eyes).

Dose Relationship

Cheilitis and hypertriglyceridemia are usually dose related. Most adverse reactions reported in clinical trials were reversible when therapy was discontinued;).**WARNINGS and ADVERSE REACTIONS**however, some persisted after cessation of therapy (see

Body as a Whole

), edema, fatigue, lymphadenopathy, weight loss**PRECAUTIONS: Hypersensitivity** allergic reactions, including vasculitis, systemic hypersensitivity (see

Cardiovascular

palpitation, tachycardia, vascular thrombotic disease, stroke

Endocrine/Metabolic

)**PRECAUTIONS: Laboratory Tests**), alterations in blood sugar levels (see**WARNINGS: Lipids** hypertriglyceridemia (see

Gastrointestinal

WARNINGS:), pancreatitis (see**WARNINGS: Hepatotoxicity**), hepatitis (see**WARNINGS: Inflammatory Bowel Disease** inflammatory bowel disease (see), bleeding and inflammation of the gums, colitis, esophagitis/esophageal ulceration, ileitis, nausea, other nonspecific gastrointestinal symptoms**Lipids**

Hematologic

PATIENT), anemia, thrombocytopenia, neutropenia, rare reports of agranulocytosis (see**PRECAUTIONS: Hypersensitivity** allergic reactions (see for other hematological parameters. **PRECAUTIONS: Laboratory Tests**). See**INFORMATION**

Musculoskeletal

), **WARNINGS: Skeletal** skeletal hyperostosis, calcification of tendons and ligaments, premature epiphyseal closure, decreases in bone mineral density (see), transient pain in the chest **PATIENT INFORMATION**musculoskeletal symptoms (sometimes severe) including back pain, myalgia, and arthralgia (see **PRECAUTIONS:**), arthritis, tendonitis, other types of bone abnormalities, elevations of CPK/rare reports of rhabdomyolysis (see**PATIENT INFORMATION** (see).**Laboratory Tests**

Neurological

), dizziness, drowsiness, headache, insomnia, lethargy, malaise, nervousness, paresthesias, **WARNINGS: Pseudotumor Cerebri** pseudotumor cerebri (see seizures, stroke, syncope, weakness

Psychiatric

), emotional instability**WARNINGS: Psychiatric Disorders** suicidal ideation, suicide attempts, suicide, depression, psychosis, aggression, violent behaviors (see

Of the patients reporting depression, some reported that the depression subsided with discontinuation of therapy and recurred with reinstitution of therapy.

Reproductive System

abnormal menses

Respiratory

bronchospasms (with or without a history of asthma), respiratory infection, voice alteration

Skin and Appendages

erythema [7]acne fulminans, alopecia (which in some cases persists), bruising, cheilitis (dry lips), dry mouth, dry nose, dry skin, epistaxis, eruptive xanthomas, multiforme, flushing, fragility of skin, hair abnormalities, hirsutism, hyperpigmentation and hypopigmentation, infections (including disseminated herpes simplex), nail dystrophy, paronychia, peeling of palms and soles, photoallergic/photosensitizing reactions, pruritus, pyogenic granuloma, rash (including facial erythema, seborrhea, and eczema), Stevens-Johnson syndrome, sunburn susceptibility increased, sweating, toxic epidermal necrolysis, urticaria, vasculitis (including), abnormal wound healing (delayed healing or exuberant granulation tissue with crusting; **PRECAUTIONS: Hypersensitivity**Wegener's granulomatosis; see)**PATIENT INFORMATION**see

Special Senses

), tinnitus.**WARNINGS: Hearing Impairment** hearing impairment (see- ***Hearing***

), cataracts, **WARNINGS: Decreased Night Vision**), decreased night vision which may persist (see**WARNINGS: Corneal Opacities** corneal opacities (see- ***Vision*** color vision disorder, conjunctivitis, dry eyes, eyelid inflammation, keratitis, optic neuritis, photophobia, visual disturbances

Urinary System

for other urological **PRECAUTIONS: Laboratory Tests**), nonspecific urogenital findings (see**PRECAUTIONS: Hypersensitivity** glomerulonephritis (see parameters)

Laboratory

), decrease in serum high-density lipoprotein (HDL) levels, elevations of serum cholesterol during **WARNINGS: Lipids** Elevation of plasma triglycerides (see treatment

)**WARNINGS: Hepatotoxicity** Increased alkaline phosphatase, SGOT (AST), SGPT (ALT), GGTP or LDH (see

), hyperuricemia**PRECAUTIONS: Laboratory Tests** Elevation of fasting blood sugar, elevations of CPK (see

PATIENT Decreases in red blood cell parameters, decreases in white blood cell counts (including severe neutropenia and rare reports of agranulocytosis; see), elevated sedimentation rates, elevated platelet counts, thrombocytopenia**INFORMATION**

White cells in the urine, proteinuria, microscopic or gross hematuria