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Absorica (Isotretinoin)

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

The following adverse reactions with ABSORICA or other isotretinoin products are described in more detail in other sections of the labeling:

- **WARNINGS AND PRECAUTIONS** Embryofetal Toxicity [see]
- **WARNINGS AND PRECAUTIONS** Psychiatric Disorders [see]
- **WARNINGS AND PRECAUTIONS** Pseudotumor Cerebri [see]
- **WARNINGS AND PRECAUTIONS** Serious Skin Reactions [see]
- **WARNINGS AND PRECAUTIONS** Pancreatitis [see]
- **WARNINGS AND PRECAUTIONS** Lipid Abnormalities [see]
- **WARNINGS AND PRECAUTIONS** Hearing Impairment [see]
- **WARNINGS AND PRECAUTIONS** Hepatotoxicity [see]
- **WARNINGS AND PRECAUTIONS** Inflammatory Bowel Disease [see]
- **WARNINGS AND PRECAUTIONS** Skeletal Abnormalities [see]
- **WARNINGS AND PRECAUTIONS** Ocular Abnormalities [see]
- **WARNINGS AND PRECAUTIONS** Hypersensitivity [see]

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of ABSORICA cannot be directly compared to rates in clinical trials of other drugs and may not reflect the rates observed in practice.

The adverse reactions listed below reflect both clinical experience with ABSORICA, and consider other adverse reactions that are known from clinical trials and the post-marketing surveillance with oral isotretinoin. The relationship of some of these events to isotretinoin therapy is unknown. Many of the side effects and adverse events seen in patients receiving isotretinoin are similar to those described in patients taking very high doses of vitamin A (dryness of the skin and mucous membranes, e.g., of the lips, nasal passage, and eyes).

Dose Relationship

Cheilitis and hypertriglyceridemia are adverse reactions that are usually dose related. Most adverse reactions reported in clinical trials with isotretinoin were reversible when therapy was discontinued; however, some persisted after cessation of therapy.

Body as a Whole

The following adverse reactions have been reported in a clinical trial conducted with ABSORICA and a generic product of Accutane® (isotretinoin): fatigue, irritability, pain. In addition to the above adverse reactions, the following adverse reactions have been reported with isotretinoin: allergic reactions, including vasculitis, systemic hypersensitivity, edema, lymphadenopathy, weight loss.

Cardiovascular

The following adverse reactions have been reported with isotretinoin: vascular thrombotic disease, stroke, palpitation, tachycardia.

Endocrine/Metabolism and Nutritional

The following adverse reactions have been reported in a clinical trial conducted with ABSORICA and a generic product of Accutane® (isotretinoin): decreased appetite, weight fluctuation, hyperlipidaemia. In addition to the above adverse reactions, the following adverse reactions have been reported with isotretinoin: hypertriglyceridemia, alterations in blood sugar.

Gastrointestinal

The following adverse reactions have been reported in a clinical trial conducted with ABSORICA and a generic product of Accutane® (isotretinoin): lip dry, chapped lips, cheilitis, nausea, constipation, diarrhea, abdominal pain, vomiting. In addition to the above adverse reactions, the following adverse reactions have been reported with isotretinoin: inflammatory bowel disease, hepatitis, pancreatitis, bleeding and inflammation of the gums, colitis, esophagitis/esophageal ulceration, ileitis, and other nonspecific gastrointestinal symptoms.

Hematologic

The following adverse reactions have been reported with isotretinoin: allergic reactions, anemia, thrombocytopenia, neutropenia, rare reports of agranulocytosis.

Infections and infestations

The following adverse reactions have been reported in a clinical trial conducted with ABSORICA and a generic product of Accutane® (isotretinoin): nasopharyngitis, hordeolum, upper respiratory tract infection. In addition to the above adverse reactions, the following adverse reaction has been reported with isotretinoin: infections (including disseminated herpes simplex).

Laboratory Abnormalities

The following changes in laboratory tests have been noted in a clinical trial conducted with ABSORICA and a generic product of Accutane® (isotretinoin): blood creatine phosphokinase (CPK) increased, blood triglycerides increased, alanine aminotransferase (SGPT) increased, aspartate aminotransferase (SGOT) increased, gamma-glutamyltransferase (GGTP) increased, blood cholesterol increased, low density lipoprotein (LDL) increased, white blood cell count decreased, blood alkaline phosphatase increased, blood bilirubin increased, blood glucose increased, high density lipopoprotein (HDL) decreased, bone mineral density decreased. In addition to the above adverse reactions, the following adverse reactions have been reported with isotretinoin: increased LDH, elevation of fasting blood sugar, hyperuricemia, decreases in red blood cell parameters, decreases in white blood cell counts (including severe neutropenia and rare reports of agranulocytosis), elevated sedimentation rates, elevated platelet counts, thrombocytopenia, white cells in the urine, proteinuria, microscopic or gross hematuria.

Musculoskeletal and Connective Tissue

The following adverse reactions have been reported in a clinical trial conducted with ABSORICA and a generic product of Accutane® (isotretinoin): decreases in bone mineral density, musculoskeletal symptoms (sometimes severe) including back pain, athralgia, musculoskeletal discomfort, musculoskeletal pain, neck pain,]. In addition to the above adverse reactions, the following adverse **WARNINGS AND PRECAUTIONS**pain in extremity, myalgia, musculoskeletal stiffness [see reactions have been reported with isotretinoin: skeletal hyperostosis, calcification of tendons and ligaments, premature epiphyseal closure, tendonitis, arthritis, transient pain in the chest, and rare reports of rhabdomyolysis.

Neurological

The following adverse reactions have been reported in a clinical trial conducted with ABSORICA and a generic product of Accutane® (isotretinoin): headache, syncope. In addition to the above adverse reactions, other adverse reactions reported with isotretinoin include: pseudotumor cerebri, dizziness, drowsiness, lethargy, malaise, nervousness, paresthesias, seizures, stroke, weakness.

Psychiatric

The following adverse reactions have been reported in clinical trials conducted with ABSORICA and a generic product of Accutane® (isotretinoin): suicidal ideation, insomnia, anxiety, depression, irritability, panic attack, anger, euphoria, violent behaviors, emotional instability. In addition to the above adverse reactions, the following adverse reactions have been reported with isotretinoin: suicide attempts, suicide, aggression, psychosis and hallucination auditory. Of the patients reporting depression, some reported that the depression subsided with discontinuation of therapy and recurred with reinstitution of therapy.

Reproductive System

The following adverse reaction has been reported with isotretinoin: abnormal menses.

Respiratory

The following adverse reactions have been reported in a clinical trial conducted with ABSORICA and a generic product of Accutane® (isotretinoin): epistaxis, nasal dryness. In addition to the above adverse reactions, the following adverse reactions have been reported with isotretinoin: bronchospasms (with or without a history of asthma), respiratory infection, voice alteration.

Skin and Subcutaneous Tissue

The following adverse reactions have been reported in a clinical trial conducted with ABSORICA and a generic product of Accutane® (isotretinoin): dry skin, dermatitis, eczema, rash, dermatitis contact, alopecia, pruritus, sunburn, erythema. In addition to the above adverse reactions, the following adverse reactions have been reported with isotretinoin: acne fulminans, alopecia (which in some cases persists), bruising, dry nose, eruptive xanthomas, erythema multiforme, flushing, fragility of skin, hair abnormalities, hirsutism, hyperpigmentation and hypopigmentation, 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 Wegener's granulomatosis), abnormal wound healing (delayed healing or exuberant granulation tissue with crusting).

Special Senses

The following adverse reactions have been reported with isotretinoin: tinnitus and hearing impairment. **Hearing:**

The following adverse reactions have been reported in clinical trials conducted with ABSORICA and a generic product of Accutane® (isotretinoin): dry eye, **Ocular:** visual acuity reduced, vision blurred, eye pruritis, eye irritation, asthenopia, decreased night vision, ocular hyperemia, increased lacrimation, and conjunctivitis. In addition to the above adverse reactions, the following adverse reactions have been reported with isotretinoin: corneal opacities, decreased night vision which may persist, cataracts, color vision disorder, conjunctivitis, eyelid inflammation, keratitis, optic neuritis, photobia, visual disturbances.

Renal and Urinary

The following adverse reactions have been reported in clinical trials conducted with isotretinoin: glomerulonephritis, nonspecific urogenital findings.