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Danocrine (Danazol)

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

The following events have been reported in association with the use of DANOCRINE:

Androgen like effects include weight gain, acne and seborrhea. Mild hirsutism, edema, hair loss, voice change, which may take the form of hoarseness, sore throat or of instability or deepening of pitch, may occur and may persist after cessation of therapy. Hypertrophy of the clitoris is rare.

Other possible endocrine effects are menstrual disturbances including spotting, alteration of the timing of the cycle and amenorrhea. Although cyclical bleeding and ovulation usually return within 60-90 days after discontinuation of therapy with DANOCRINE, persistent amenorrhea has occasionally been reported.

Flushing, sweating, vaginal dryness and irritation and reduction in breast size, may reflect lowering of estrogen. Nervousness and emotional lability have been reported. In the male a modest reduction in spermatogenesis may be evident during treatment. Abnormalities in semen volume, viscosity, sperm count, and motility may occur in patients receiving long-term therapy.

Hepatic dysfunction, as evidenced by reversible elevated serum enzymes and/or jaundice, has been reported in patients receiving a daily dosage of DANOCRINE of 400 mg or more. It is recommended that patients receiving DANOCRINE be monitored for hepatic dysfunction by laboratory tests and clinical observation. Serious .) **PRECAUTIONS**and**WARNINGS** hepatic toxicity including cholestatic jaundice, peliosis hepatis, and hepatic adenoma have been reported. (See

Abnormalities in laboratory tests may occur during therapy with DANOCRINE including CPK, glucose tolerance, glucagon, thyroid binding globulin, sex hormone binding globulin, other plasma proteins, lipids and lipoproteins.

: urticaria, *allergic* The following reactions have been reported, a causal relationship to the administration of DANOCRINE has neither been confirmed nor refuted; : headache, nervousness and emotional lability, dizziness and fainting, depression, fatigue, sleep disorders, *effects CNS*pruritus and rarely, nasal congestion; tremor, paresthesias, weakness, visual disturbances, and rarely, benign intracranial hypertension, anxiety, changes in appetite, chills, and rarely convulsions, : muscle *musculoskeletal* : gastroenteritis, nausea, vomiting, constipation, and rarely, pancreatitis and splenic peliosis;*gastrointestinal*Guillain-Barre syndrome; cramps or spasms, or pains, joint pain, joint lockup, joint swelling, pain in back, neck, or extremities, and rarely, carpal tunnel syndrome which may be secondary to : an increase in red cell and platelet count. Reversible erythrocytosis, *hematologic* : hematuria, prolonged posttherapy amenorrhea;*genitourinary*fluid retention; : rashes (maculopapular, vesicular, *Skin*leukocytosis or polycythemia may be provoked. Eosinophilia, leukopenia and thrombocytopenia have also been noted. : increased insulin requirements in diabetic *other*papular, purpuric, petechial), and rarely, sun sensitivity, Stevens-Johnson syndrome and erythema multiforme; patients, change in libido, myocardial infarction, palpitation, tachycardia, elevation in blood pressure, interstitial pneumonitis, and rarely, cataracts, bleeding gums, fever, pelvic pain, nipple discharge. Malignant liver tumors have been reported in rare instances, after long-term use.