Taj Pharmaceuticals Ltd.

Danazol

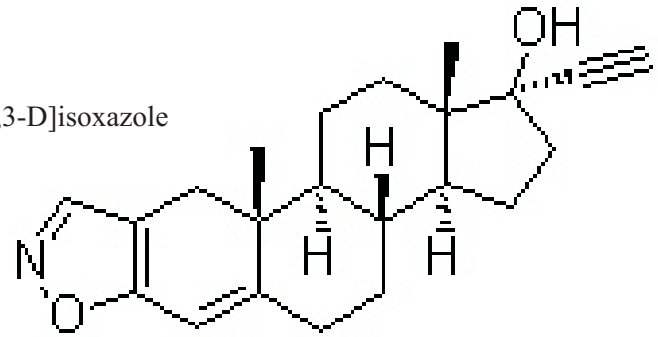
CAS No. : 17230-88-5

Synonyms

17alpha-Pregna-2,4-dien-20-yno[2,3-d]isoxazol-17-ol;
17beta-Hydroxy-2,4,17alpha-pregnadien-20-yno[2,3-d]
isoxazole; 2,4,17alpha-Pregnadien-20-yno[2,3-d]-isoxa-zol-17-ol

Molecular Structure

Danazol Molecular Formula C22H27NO2
Molecular Formula C22H27NO2
Molecular Weight 337.46
CAS Number 17230-88-5
EINECS 241-270-1
Mol. mass 337.5 g/mol
Synonyms 17β-hydroxy-2,4,17a-pregnadien-20-yno[2,3-D]isoxazole



Pharmacokinetic data

Bioavailability ?
Metabolism Hepatic
Half life 15 hours
Excretion ?

DOSAGE

In moderate to severe disease, or in patients infertile due to endometriosis, a starting dose of 800 mg given in two divided doses is recommended. Amenorrhea and rapid response to painful symptoms is best achieved at this dosage level. Gradual downward titration to a dose sufficient to maintain amenorrhea may be considered depending upon patient response. For mild cases, an initial daily dose of 200 mg to 400 mg given in two divided doses is recommended and may be adjusted depending on patient response. Therapy should begin during menstruation. Otherwise, appropriate tests should be performed to ensure that the patient is not pregnant while on therapy with Danazol.It is essential that therapycontinue uninterrupted for 3 to 6 months but may be extended to 9 months if necessary. After termination of therapy, if symptoms recur, treatment can be reinstituted.

SIDE EFFECTS

May cause dizziness, headache, fatigue, appetite changes, stomach upset, bloating, or anxiety. These effects should disappear as your body adjusts to the medication. Other side effects reported include oily skin, weight gain, flushing, changes in sleep patterns, change in sex drive, muscle cramps, chills, fluid retention in the hands or feet or nasal congestion. Notify your doctor if any of these become bothersome. Notify your doctor if you experience: depression, hot flashes, deepening of the voice, abnormal growth of fine body hair or facial hair, vision changes, yellowing of the eyes or skin, one-sided weakness, slurred speech. Women often experience no or irregular menstrual periods while taking this medication. Menstrual periods usually return within 90 days of stopping the drug. If you notice other effects not listed above, contact your doctor or pharmacist.
Androgenic side effects are of concern, because in sensitive female patients, danazol can enhance unwanted hair growth, leading to hirsutism. On rare occasion, it can deepen the voice. Other possible side effects include acne and oily skin.

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Because danazol is metabolized by the liver, it cannot be used by patients with liver disease, and in patients receiving long-term therapy, liver function must be monitored on a periodic basis.Some patients who use danazol experience weight gain and fluid retention. Due to these limitations, danazol is seldom prescribed continuously beyond six months.

The use of danazol for endometriosis has been linked to an increased risk of ovarian cancer.

Patients with endometriosis have specific risk factors for ovarian cancer so this may not apply for other uses.

Danazol has, like most other androgenic agents, been linked with an increased risk of liver tumors.

PRECAUTIONS

Use of Danazol in pregnancy is contraindicated. A sensitive test (e.g., beta subunit test if available) capable of determining early pregnancy is recommended immediately prior to start of therapy. Additionally a nonhormonal method of contraception should be used during therapy. If a patient becomes pregnant while taking Danazol, administration of the drug should be discontinued and the patient should be apprised of the potential risk to the fetus. Exposure to Danazol in utero may result in androgenic effects on the female fetus; reports of clitoral hypertrophy, labial fusion, urogenital sinus defect, vaginal atresia, and ambiguous genitalia have been received. (See PRECAUTIONS: Pregnancy, Teratogenic Effects.)

Thromboembolism, thrombotic and thrombophlebitic events including sagittal sinus thrombosis and life-threatening or fatal strokes have been reported.

Experience with long-term therapy with Danazol is limited. Peliosis hepatis and benign hepatic adenoma have been observed with long-term use. Peliosis hepatis and hepatic adenoma may be silent until complicated by acute, potentially life-threatening intra-abdominal hemorrhage. The physician therefore should be alert to this possibility. Attempts should be made to determine the lowest dose that will provide adequate protection. If the drug was begun at a time of exacerbation of hereditary angioneurotic edema due to trauma, stress or other cause, periodic attempts to decrease or withdraw therapy should be considered.

Danazol has been associated with several cases of benign intracranial hypertension also known as pseudotumor cerebri. Early signs and symptoms of benign intracranial hypertension include papilledema, headache, nausea and vomiting, and visual disturbances. Patients with these symptoms should be screened for papilledema and, if present, the patients should be advised to discontinue Danazol immediately and be referred to a neurologist for further diagnosis and care.

A temporary alteration of lipoproteins in the form of decreased high density lipoproteins and possibly increased low density lipoproteins has been reported during Danazol therapy. These alterations may be marked, and prescribers should consider the potential impact on the risk of atherosclerosis and coronary artery disease in accordance with the potential benefit of the therapy to the patient.

Before initiating therapy of fibrocystic breast disease with Danazol, carcinoma of the breast should be excluded. However, nodularity, pain, tenderness due to fibrocystic breast disease may prevent recognition of underlying carcinoma before treatment is begun. Therefore, if any nodule persists or enlarges during treatment, carcinoma should be considered and ruled out.

Patients should be watched closely for signs of androgenic effects some of which may not be reversible even when drug administration is stopped.

DRUG DESCRIPTION

Danazol is a synthetic steroid derived from ethisterone. Chemically, Danazol is 17a-Pregna-2,4-dien-20-yno[2,3-d]-isoxazol-17-ol

Each capsule, for oral administration, contains 50 mg, 100 mg or 200 mg of Danazol. In addition, each capsule contains the following inactive ingredients: lactose monohydrate, magnesium stearate, sodium starch glycolate, and stearic acid.

The capsule shell contains D&C yellow no. 10, gelatin, silicon dioxide, sodium lauryl sulfate, and titanium dioxide. The 50 mg and 100 mg capsule shells also contain FD&C yellow no. 6. The 200 mg capsule shell also contains FD&C red no. 40 and D&C red no. 28.

The imprinting ink contains black iron oxide, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, FD&C blue no. 2 aluminum lake, FD&C red no. 40 aluminum lake, pharmaceutical glaze, and propylene glycol.

This medication is a synthetic hormone. It is used to treat pain and infertility caused by endometriosis, a condition involving the tissue of the uterus. It is also used in the treatment of cysts or lumps in the breast or may be prescribed for heavy menstrual flow.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

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