**Composition**

Danol 200 mg capsules: Pink/White No. 1 hard gelatin capsules printed in black ink with Danol 200 and filled with a white or almost white powder containing 200 mg danazol and lactose.

Danol 100 mg capsules: Grey/White No. 3 hard gelatin capsules printed in black ink with Danol 100 and filled with a white or almost white powder containing 100 mg danazol and lactose.

**Indications**

Endometriosis, to control pain, pelvic tenderness and other associated symptoms and to resolve or reduce the extent of endometriotic foci. Danol may be used as sole therapy or in preparation for, or following, surgery.

Severe cyclic mastalgia with or without nodularity (fibrocystic breast disease, mazoplasia, mastodynia), not responsive to counselling or simple analgesics, to reduce pain, tenderness and nodularity.

Benign, multiple or recurrent breast cysts to reduce the need for surgical aspiration. Dysfunctional uterine bleeding, presenting as menorrhagia, to control excessive blood loss and associated dysmenorrhea. Preparation for hysteroscopic endometrial ablation to thin the endometrium and facilitate surgery.

Hereditary angioedema to correct partially or completely the underlying biochemical abnormality and its clinical consequences.

Severe symptomatic gynecomastia, both idiopathic as well as drug induced, to reduce the size of the breast and to control associated pain and tenderness.

**Contraindications**


Undiagnosed abnormal genital bleeding.

**Side Effects**

For the most part, recognized side effects are predictable and reversible. Clinically serious side effects are uncommon.

Androgenic events include weight gain, acne, seborrhea, hirsutism, hair loss, voice change, and clitoral hypertrophy.

Other endocrine events include disturbance of the menstrual cycle, intermenstrual spotting, amenorrhea, flushing, vaginal dryness, vaginal irritation, reduction in breast size and reduction in spermatogenesis.

Metabolic events include increased insulin resistance and elevation of plasma glucagon. An increase in LDL cholesterol, a decrease in HDL cholesterol affecting all subfractions and a decrease in apolipoproteins A1 and AII have been reported. The clinical significance of these changes is not established. Other metabolic events include induction of aminolevulinic acid (ALA) synthetase and reduction in thyroid binding globulin and T4 with increased uptake of T3, but without disturbance of thyroid stimulating hormone or of free thyroxine index.

Dermatological events include maculopapular, petechial, purpuric and urticarial rashes, sometimes associated with facial edema, fever or sun-sensitivity.

Inflammatory erythematous nodules, altered skin pigmentation and exfoliative dermatitis have also been observed.

Musculoskeletal events include backache, muscle cramps, sometimes with elevation of creatinine phosphokinase levels, muscle tremors, fasciculation, limb pain, joint pain and joint swelling.

Cardiovascular events include exacerbation of hypertension, palpitation and tachycardia. Thrombotic events have also been observed, including sagittal sinus and cerebrovascular thrombosis.

Ophthalmic events include visual disturbances such as...
renal disease; hypertension or other cardiovascular disease; any state which may be exacerbated by fluid retention; diabetes mellitus; polycythemia; epilepsy; lipoprotein disorder; a history of thrombosis or thromboembolic disease; a history of marked or persistent androgenic reaction to previous gonadal steroid therapy; migraine. Close clinical monitoring is advised in all patients. Laboratory monitoring should also be considered including periodic measurement of hepatic function and hematological state.

Before treatment initiation, the presence of carcinoma should be excluded as well as if breast nodules persist or enlarge during danazol treatment. The lowest effective dose of danazol should always be sought.

Pregnancy and Lactation

Pregnancy: Since danazol is contraindicated in pregnancy because of a risk of virilization to the female fetus, appropriate steps should be taken in women of childbearing age to exclude the possibility of pregnancy before starting therapy. Danazol should be initiated during menstruation. An effective, nonhormonal method of contraception should be employed. If a patient conceives during therapy, danazol should be stopped.

Lactation: Danazol has the theoretical potential for androgenic effects in breastfed infants and therefore either danazol therapy or breast-feeding should be discontinued.

Overdosage

Available evidence suggests that acute overdosage would be unlikely to give rise to immediate serious reaction.

Nonetheless, consideration should be given to removal of the drug by emesis or stomach pump and the patient should be kept under observation in case of any delayed reactions.

Drug Interactions

Anticonvulsant Drugs: Danazol can increase plasma level of carbamazepine and may affect responsiveness to this agent and to phenytoin. A similar interaction with phenobarbital is likely.
Antidiabetic drugs: Danazol can cause insulin resistance.

Oral Anticoagulants: Danazol can potentiate the action of warfarin.

Antihypertensive drugs: Danazol can diminish the effectiveness of antihypertensive agents.

Cyclosporin: Danazol can increase the plasma level of cyclosporin.

Concomitant steroids: it is likely that interactions between Danazol and gonadal steroid therapy would occur.

Other Drug Interactions: Danazol can increase the calcemic response to alpha calcidol in primary hypoparathyroidism.

Interactions with laboratory function tests: Danazol treatment may interfere with laboratory determination of testosterone or plasma proteins (see Pharmacodynamics and Side effects).

Dosage and Administration
For oral administration only.

Adults: Danol should be given as a continuous course, dosage being adjusted according to the patient’s response. A reduction in dosage once a satisfactory response has been achieved may prove possible. In fertile females, Danol should be started during menstruation, to avoid exposing a pregnancy to its possible effects, and nonhormonal contraception should be employed throughout the course of treatment (see Warnings and Precautions).

Endometriosis: The recommended dosage is 200 mg to 800 mg daily, a course of treatment lasting normally six months, although up to nine months may be necessary in some cases.

Severe cyclical mastalgia: Dosage and Administration normally ranges from 100 mg to 400 mg daily, a course of treatment lasting normally 3-6 months.

Benign Breast Cysts: Dosage and Administration normally ranges from 100 mg to 400 mg daily, a course of treatment normally lasting 3-6 months.

Dysfunctional Uterine Bleeding Presenting as Menorrhagia: the dosage should be 200 mg daily, normally for 3 months.

Preparation for hysteroscopic endometrial ablation: 400 mg to 800 mg per day for 3 to 6 weeks is recommended.

Gynecomastia: A six month course of therapy is recommended at a dose of 200 mg daily in adolescents, which may be increased to 400 mg daily if no response is obtained after two months.

Adults may be given 400 mg daily.

Hereditary Angioedema: an initial dosage of 200 mg two or three times a day is recommended. Following a favorable response, the lowest effective maintenance dose should be sought and reduction in dosage of up to 50 percent may be attempted at intervals of one to three months or longer depending on the patient’s history and clinical response.

Elderly: Danol is not recommended.

Children: Danol is not recommended.

Packaging
ca: 200 mg x 100
100 mg x 100.