

Lozana[®] 100 & 200

Danazol 100 & 200 mg capsule

Presentation

Lozana[®] 100: Each capsule contains Danazol USP 100 mg.
Lozana[®] 200: Each capsule contains Danazol USP 200 mg.

Description

Lozana is a weak impeded androgen with associated anabolic properties. It inhibits gonadotropin-releasing hormone and gonadotropin secretion. This suppresses menstruation, inhibits ovulation, and causes regressive change in the vaginal smear and atrophic change in the endometrium. Danazol has no estrogenic or progestational properties.

Indications and use

Lozana is indicated for the following treatment of

- Endometriosis
- Benign breast disease
- Menorrhagia
- Gynecomastia
- Preoperative thinning of the endometrium before hysteroscopic endometrial ablation.

Dosages and Administrations

Lozana is available for oral administration only. Dosage depends on the condition being treated and the patient's response. For adults, the dosage lies between 200 mg and 800 mg daily in two to four divided doses. It is recommended that danazol therapy in adult females should start on the first day of the menstrual cycle with an adjustment of dosage made subsequently to achieve amenorrhoea or the desired effect. *In endometriosis:* The initial dose is 400 mg daily usually continued for 6 months. If symptoms do not resolve, the dose can be increased to 800 mg daily but the total course should not exceed 9 months. *Benign breast disease:* Severe cyclical mastalgia. The recommended initial dose for severe cyclical mastalgia is 200-300 mg daily for 3-6 months. In several studies, the initial dose of danazol was either 200 mg or 300 mg daily, which was reduced after either 1 or 2 months if a clinically useful response had occurred. *Benign, multiple or recurrent breast disease:* The recommended initial dose for this indication is 300 mg daily for 3-6 months. *Menorrhagia:* In menorrhagia, daily doses of 100-200 mg have been found effective but 200 mg daily is usually sufficient to reduce menstrual blood flow to acceptable levels. The recommended initial dose is 200 mg daily for 3 months. *Gynecomastia:* Adults, 300-600 mg daily. Adolescents, 200-300 mg daily. *Preoperative thinning of the endometrium before hysteroscopic endometrial ablation:* Danazol induces endometrial atrophy and is currently recommended at doses of 400-800 mg daily for up to 3 months preoperatively.

Contraindications

- Pregnancy and breast-feeding
- Impaired hepatic, renal, or cardiac function
- Porphyria
- Thromboembolic disease
- Androgen-dependent tumor
- Abnormal vaginal bleeding that has not been fully investigated.
- Hypersensitivity to danazol.

Side effects

Potentially life-threatening effects: None has been reported. *Severe or irreversible adverse effects:* If signs of virilization occur, e.g; voice changes or hirsutism, danazol therapy should be stopped immediately. *Symptomatic adverse effect:* Danazol has androgenic side effects causing acne, hair growth, oily skin, edema and weight gain, and these effects are dose related.

Other adverse effects: Include menstrual disturbances, hypo-estrogenic symptoms, such as flushing, vaginal dryness and irritation and a modest reduction of spermatogenesis in the male. Maculopapular, petechial, purpuric and urticarial rashes have been reported. Cardiovascular reactions may include exacerbation of hypertension, palpitations and tachycardia. Various psychological reactions such as increased appetite, emotional lability, anxiety, depression, nervousness, changes in libido, dizziness, vertigo, nausea, headache and fatigue have been described.

High risk group

Neonates: The drug is not recommended in this age group. *Children:* Danazol is not used in children. *Pregnant women:* The drug should not be given to pregnant patients, because of the risk of virilization of a female fetus, particularly when high doses are given for several weeks. *Lactating mother:* Patients taking the drug should not breast-feed. *Concurrent disease:* Because Danazol may cause some degree of fluid retention, patients with condition which may be influenced by this factor such as cardiac or renal dysfunction, epilepsy or migraine require careful observation.

Drug interactions

Insulin: Patients taking danazol may show increased insulin resistance. The significance of this is not known but such patients should be carefully monitored. *Estrogens and progestogens:* Theoretically danazol may interact with exogenous estrogens and/or progestogens. It has been suggested that danazol acts by binding to estrogen, progesterone or androgen receptors at various levels in the hypothalamic pituitary-ovarian axis. Therefore, women of child bearing age should use effective, non hormonal methods of contraception. *Anticonvulsant therapy:* Danazol may affect the plasma concentration of carbamazepin and possibly the patient's response to this agent and to phenytoin. A similar interaction is possible for phenobarbital. *Antihypertensive therapy:* Danazol can oppose the action of antihypertensive agents, possibly through effects on fluid retention. *Cyclosporine:* Danazol can increase the plasma concentration of cyclosporine. *Migraine therapy:* Danazol itself may provoke migraine and it may possibly reduce the effectiveness of medication to prevent the condition.

Overdosage

There have been no incidents of acute overdosage with Danazol and it is unlikely that any immediate serious reaction will be seen from a single excessive dose. In case of the acute overdosage, the drug should be removed by gastric lavage and the patient should be kept under observation.

Commercial Pack

Lozana[®]100: Each box contains 5 blister strips of 4 capsules.
Lozana[®]200: Each box contains 4 blister strips of 4 capsules.

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