

**Composition : Endozol 100 Capsule :** Each Capsule Contains Danazol BP 100 mg.

**Endozol 200 Capsule :** Each Capsule Contains Danazol BP 200 mg.

**Pharmacology :** Danazol 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. It has no estrogenic or progestogenic properties.

**Indications :** It is indicated for the treatment of Endometriosis, Benign breast disease, Severe cyclical mastalgia, Menorrhagia, Gynaecomastia, Preoperative thinning of the endometrium before hysteroscopic endometrial ablation.

**Dosage and administration :** Usually given in up to 4 divided doses, in women of child bearing potential, treatment should start during menstruation, preferably on first day.

**Endometriosis :** 200-800mg daily in up to 4 divided doses, adjusted to achieve amenorrhoea, usually for 6 months (up to 9 months in some cases).

**Benign breast cysts :** 300mg daily usually for 3-6 months. **Severe cyclical mastalgia :** 100-400mg daily usually for 3-6 months. **Menorrhagia :** In menorrhagia daily doses of 100-200mg have been found effective but 200mg daily for 3 months is usually sufficient to reduce menstrual blood flow to acceptable levels. **Gynaecomastia :** 400mg daily in up to 4 divided doses for 6 months (adolescents 200mg daily, increased to 400mg daily if no response after 2 months). **For pre-operative thinning of endometrium:** 400-800mg daily in up to 4 divided doses for 3-6 weeks. Or, as directed by the registered physician.

**Contraindication :** It is contraindicated in patients with pregnancy and breast feeding, impaired hepatic, renal or cardiac function, thromboembolic disease, androgen-dependent tumor, abnormal vaginal bleeding that has not been fully investigated, hypersensitivity to danazol or any other components of this product.

## Endozol Capsule



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**Precaution :** Caution should be taken when danazol is used in patients with cardiac, hepatic or renal impairment, elderly, polycythaemia, epilepsy, diabetes mellitus, hypertension, migraine, lipoprotein disorder, history of thrombosis or thromboembolic disease. If signs of virilization occur e.g. voice changes or hirsutism, therapy should be stopped immediately.

**Side effects :** Side effects include: nausea, dizziness, skin reactions including rashes, photosensitivity and exfoliative dermatitis, fever, backache, nervousness, mood changes, anxiety, changes in libido, vertigo, fatigue, epigastric and pleuritic pain, headache, weight gain; menstrual disturbances, vaginal dryness and irritation, flushing and reduction in breast size; musculo-skeletal spasm, joint pain and swelling, hair loss; androgenic effects including acne, oily skin, oedema, hirsutism, voice changes and rarely clitoral hypertrophy; temporary alteration in lipoproteins and other metabolic changes, insulin resistance; thrombotic events; leucopenia, thrombocytopenia, eosinophilia, reversible erythrocytosis or polycythaemia headache and visual disturbances may indicate benign intracranial hypertension.

**Use in pregnancy and lactation :** The drug should not be given to pregnant women, because of risk of virilization of a female fetus, particularly when high doses are given for several weeks. Patients taking the drug should not breast feed.

**Use in child :** There is no data available.

**Drug interactions :** There is no data available.

**Overdose :** There is no data available.

**Storage :** Store below 30°C in a dry place.

**Packing : Endozol 100 Capsule :** Each box contains 30's capsule in blister pack.

**Endozol 100 Capsule :** Each box contains 20's capsule in blister pack.