

DANAZOL

DANAZOL USP

Compositions:

Danazol-100 Capsule: Each capsule contains Danazol USP 100 mg
Danazol-200 Capsule: Each capsule contains Danazol USP 200 mg

Pharmacology:

Danazol is a preparation of Danazole. It 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 progestogenic properties.

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—800 mg daily in up to 4 divided doses, adjusted to achieve amenorrhoea, usually for 6 months (up to 9 months in some cases). Menorrhagia: In menorrhagia daily doses of 100-200 mg have been found effective but 200 mg daily for 3 months is usually sufficient to reduce menstrual blood flow to acceptable levels. Severe cyclical mastalgia: 100-400 mg daily usually for 3-6 months. Benign breast cysts: 300 mg daily usually for 3-6 months. Gynaecomastia: 400 mg daily in up to 4 divided doses for 6 months (adolescents 200 mg daily, increased to 400 mg daily if no response after 2 months). For pre-operative thinning of endometrium: 400 mg-800 mg daily in up to 4 divided doses for 3-6 weeks.

Contraindications:

Danazol is contraindicated in Pregnancy and breast feeding, Impaired hepatic, Renal or cardiac function, Thromboembolic disease, Androgen-dependent tumor, Abnormal vaginal bleeding, Hypersensitivity to Danazol etc.

Warning And Precaution:

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:

Weight gain, Acne, Flushing, Sweating, Voice changes (hoarseness, change in pitch), abnormal growth of body hair (in Women), vaginal dryness/ irritation, or decreased breast size may occur.

Use in Pregnancy and Lactation:

Pregnancy Category-X Pregnant Women: 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. Lactating mother: Patients taking the drug should not breast—feed.

Drug Interaction:

Insulin, Estrogen and progesteron, anticonvulsant therapy, Antihypertensive therapy, Cyclosporine, Migraine therapy.

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, or to reduce the absorption of the drug by activated charcoal, and the patient should be kept under observation in case of any delayed reactions.

Storage:

Store in a cool (below 30°C) and dry place protected from light and moisture. Keep out of the reach of children.

Packing:

Danazol-100 Capsule: Each box contains 2x10 capsules in alu-alu blister pack. Danazol-200 Capsule: Each box contains 1x10 capsules in alu-alu blister pack.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.