Danamet®

Danazol capsule

DESCRIPTION

Danamet® is a preparation of Danazol. 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. **Danamet®** has no estrogenic or progestogenic properties.

INDICATIONS

Danamet® is indicated for the treatment of the followings:

- 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: 200-800 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.

Children: **Danamet®** is not used in children.

CONTRAINDICATIONS

- 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

USE IN PREGNANCY AND LACTATION

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.

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

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 reported; headache and visual disturbances may indicate benign intracranial hypertension.

PHARMACEUTICAL PRECAUTION

Keep away from light and moisture. Keep out of reach of children.

PACKAGING

Danamet® 100 mg capsule : Box containing 2 strips of 10 capsules. Each capsule contains Danazol USP 100 mg.

Danamet® 200 mg capsule : Box containing 2 strips of 10 capsules. Each capsule contains Danazol USP 200 mg.

SK+F

Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
MIRPUR, DHAKA, BANGLADESH
® REGD. TRADEMARK
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