

FARLUTAL[®]

FARMITALIA

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Farlutal, medroxyprogesterone acetate (MAP), is a synthetic steroid active by the oral route derived from progesterone and realized in Farmitalia Carlo Erba Research Laboratories. The product has the same structure of natural progesterone, from which it differs for the presence of a methyl group in 6- α position and of an acetoxy group in 17 position. Farlutal is endowed with progestational effect and antiestrogenic and antigonadotropic activity. At suitable doses, MAP exerts its activity both on the endocrine system and on the cellular activity.

INDICATIONS - Mammary carcinoma, endometrial carcinoma, prostate carcinoma, renal carcinoma. Prostatic adenoma.

CONTRAINDICATIONS - Thrombophlebitis, thromboembolic disorders, severely impaired liver function, missed abortion, hypercalcaemia as may occur in patients with osseous metastases, metrorrhagia of unknown origin, hypersensitivity to the drug.

DOSAGE - The dosage can vary from 100 to 1000 mg/die (the higher doses can be divided into two-three daily administrations).

Commonly the lower doses have been given in endometrial carcinoma, and the higher in advanced metastatic breast carcinoma.

Farlutal may be combined with other antineoplastic treatments such as chemotherapy or radiotherapy.

SIDE EFFECTS - The following side effects have been associated with the use of Farlutal as well as of other progestins: breast tenderness, galactorrhoea, vaginal bleeding, changes in menstrual flow, amenorrhea, edema, change in weight, changes in cervical erosions or cervical secretions, cholestatic jaundice, rash with or without pruritus, psychic depression.

WARNINGS - Usage of the product during pregnancy is not recommended because of data indicating a possible association between administration of progestins early in pregnancy and congenital heart defects in the offspring. The drug should be discontinued immediately if thromboembolic disorders, sudden partial or complete loss of vision, diplopia, papilledema, retinal vascular lesions, migraine occur.

In cases of undiagnosed vaginal bleeding, adequate diagnostic measures are indicated.

If a histological examination is indicated, the laboratory should be informed that the patient has been receiving a progestogen.

The age of patients constitutes no absolute limiting factor although treatment with progestins may mask the onset of climacteric. Diabetic patients and patients who have a history of psychic depression should be carefully observed.

It should be noted that long term administration of medroxyprogesterone acetate to Beagle dogs has resulted in the development of mammary nodules which were occasionally found to be malignant.

Keep out of the reach of children.

PRESENTATIONS - Bottle of 30 tablets each containing 100 mg medroxyprogesterone acetate. Bottle of 30 tablets each containing 250 mg medroxyprogesterone acetate. Bottle of 30 tablets each containing 500 mg medroxyprogesterone acetate.



FARMITALIA CARLO ERBA

Printed in Italy

