Meganor®

Megestrol Acetate USP Tablet

DESCRIPTION

Meganor® is a preparation of Megestrol Acetate. The precise mechanism of action by which Megestrol Acetate produces its antineoplastic effects is unknown at present. Pharmacologic doses of Megestrol Acetate exerted a direct cytotoxic effect on human breast cancer cells in vitro and proved capable of modifying and abolishing the stimulatory effects of estrogen on breast cancer cell lines. Megestrol Acetate interacts with progesterone receptors to stimulate cell maturation through a progestin–inducing mechanism. It has also been shown to have certain androgenic properties and may also modify glucocorticoid action by binding to the glucocorticoid receptor.

PHARMACOKINETICS

In 24 healthy male volunteers (age 19-44 years) who received 160 mg of Megestrol Acetate given as a 40 mg q.i.d. regimen, the oral absorption of Megestrol Acetate appeared to be variable. Peak drug levels for the first 40 mg dose ranged from 10 to 56 ng/mL (mean 27.6 ng/mL) and the times to peak concentrations ranged from 1.0 to 3.0 hours (mean 2.2 hours). Plasma elimination half–life ranged from 9.9 to 104.9 hours (mean 34.2 hours). The steady state plasma concentrations for a 40 mg q.i.d. regimen have not been established. Estimates of plasma levels of Megestrol Acetate are dependent on the measurement method used. Plasma levels depend on intestinal and hepatic inactivation of the drug, which may be affected by intestinal tract mobility, intestinal bacteria, concomitant antibiotic administration, body weight, diet and hepatic function.

INDICATIONS

- For adjunctive or palliative treatment of recurrent, inoperable or metastatic carcinoma of the breast and endometrium and for palliative treatment of hormone responsive advanced (Stage D2) carcinoma of the prostate. It should not be used in lieu of currently accepted procedures such as surgery and radiation. Objective or subjective responses or arrest of tumor growth may occur for one to several months while on therapy.
- Indicated in male or female patients for the treatment of anorexia, cachexia or weight loss secondary to metastatic cancer.

DOSAGE AND ADMINISTRATION

- **For palliative or adjunctive treatment of breast carcinoma:** 160 mg or 125 mg/m2 daily (40 mg q.i.d. or 160 mg q.d.).
- **For endometrial carcinoma:** 80 - 320 mg or 62.5 - 250 mg/m2 daily in divided doses (40 - 80 mg one to four times daily or one to two 160 mg tablets daily).
- **For palliative treatment of hormone responsive advanced (Stage D2) carcinoma of the prostate:** 120 mg (93.8 mg/m2) as a single daily dose in combination with diethylstilbestrol tablet, 0.1 mg.
- **For anorexia, cachexia, or significant weight loss in patients with cancer:** usual adult dose: 400 to 800 mg as a single daily dose.

CONTRAINDICATIONS

- Hypersensitivity

SIDE EFFECTS

- Nausea, vomiting, edema
- Weight gain
- Thrombophlebitis and pulmonary embolism

OVERDOSE

Usual safety measures as with the overdose of any medication should be instituted. However, no serious unexpected side effects have resulted from studies involving Megestrol Acetate administered in dosages as high as 1600 mg/day for 6 months or more. Megestrol Acetate has not been tested for dialyzability; however, due to its low solubility, it is postulated that dialysis would not be an effective means of treating overdose.

WARNINGS AND PRECAUTIONS

Therapy with Megestrol Acetate for weight loss should only be instituted after treatable causes of weight loss are sought and addressed. These treatable causes include possible malignancies, systematic infections, gastrointestinal disorders affecting absorption, endocrine disease and renal or psychiatric disease. Use Megestrol Acetate with caution in patients with a history of thrombophlebitis. Close, customary surveillance is indicated as in any patient being treated for recurrent or metastatic cancer. Patients receiving large doses of progestational agents such as Megestrol Acetate continuously for prolonged periods should be observed closely for possible adrenal cortical suppression.

DRUG INTERACTION

Possible interactions of Megestrol Acetate with concomitant medications have not been investigated.

USE IN PREGNANCY AND LACTATION

The use of progestational agents during the first four months of pregnancy is not recommended. There is no adequate evidence that such use is effective and there is evidence of potential harm to the fetus when such drugs are given during the first four months of pregnancy. Furthermore, in the vast majority of women, the cause of abortion is a defective ovum, which progestational agents could not be expected to influence. In addition, the use of progestational agents, with their uterine–relaxant properties, in patients with fertilized defective ova may cause a delay in spontaneous abortion.

Because many drugs are excreted in human breast milk and because of the potential for adverse reactions in nursing infants, nursing should be discontinued when receiving Megestrol Acetate therapy.

PHARMACEUTICAL PRECAUTION

Store below 30 °C temperature, away from light and wet place. Keep out of reach of children.

PACKAGING

Meganor® 160 Tablet: Box containing 1 strips of 10 tablets. Each tablet contains Megestrol Acetate USP 160 mg.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LIMITED
RUPGANJ, NARAYANGANJ, BANGLADESH
® REGD. TRADEMARK
R/PM0525 V01