Meget™ 160

Megestrol Acetate USP

COMPOSITION

Meget™ 160 tablet : Each tablet contains Megestrol Acetate USP 160 mg.

DESCRIPTION

Megestrol is a white, crystalline solid chemically described as 17-Hydroxy-6-methylpregna-4, 6-diene-3, 20-dione acetate. Megestrol Acetate is chemically related to progesterone. It differs by the addition of a 17-acetoxy group, a double bond at position 6 and the presence of a methyl group. Megestrol Acetate is practically insoluble in water. Soluble in alcohol (1 in 55), chloroform (1 in 8.0), ether (1 in 130), acetone and benzyl alcohol. Slightly soluble in fixed oils.

INDICATION AND USAGE

Meget™ is a progestational agent, indicated for the treatment of certain hormone dependent neoplasms, such as breast cancer. Megestrol Acetate is also indicated in male or female patients for the treatment of anorexia, cachexia or weight loss secondary to metastatic cancer.

DOSAGE & ADMINISTRATION

Breast Cancer: 160 mg/day taken once daily. At least two months of continuous treatment is considered an adequate period for determining the efficacy of **Meget**™.

Anorexia, cachexia or significant weight loss in patients with cancer: Usual adult dose: 400-800 mg as a single dose.

Children: Safety and effectiveness in paediatric patients have not been established. **Meget**™ is not recommended for use in children.

Elderly: In general, use in elderly patients should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

CONTRAINDICATIONS

Megestrol Acetate is contraindicated in those people who are sensitive to Megestrol Acetate or any ingredients in the dosage form. It should not be used as a diagnostic test for pregnancy.

WARNINGS AND PRECAUTIONS

Meget™ should be used with caution in patients with a history of thrombophlebitis and in patients with severe impaired liver function. This product should be used under the supervision of a specialist and the patients kept under regular surveillance. This product can exert adrenocortical effects. This should be borne in mind in patient surveillance. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Insufficient data from clinical studies of Megestrol Acetate are available for patients 65 years of age and older to determine whether they respond differently than younger patients. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, use in elderly patients should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

SIDE EFFECTS

Weight gain is a frequent side effect of Megestrol Acetate when it is used in patients with cancer of the breast or endometrium. This gain is associated with increased appetite. It is this effect which forms the basis for use of megestrol acetate in patients with anorexia, cachexia or weight loss. Weight gain is associated with an increase in fat and body cell mass. Untoward reactions that have been reported to occur in patients receiving Megestrol Acetate include nausea, vomiting, edema and breakthrough uterine bleeding occur in approximately 1% to 2% of patients. Gynecomastia and loss of hearing have also been reported. Dyspnea, heart failure, hypertension, hot flashes, mood changes, cushingoid facies, tumor flare hyperglycemia, alopecia, carpal tunnel syndrome and rash have also occurred. Thromboembolic phenomenon including thrombophlebitis and pulmonary embolism (in some cases fatal) have also been reported.

DRUG INTERACTION

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

USE IN SPECIFIC POPULATION

Pregnancy: Megestrol Acetate is not recommended for women who are pregnant.

Several reports suggest an association between intrauterine exposure to progestational drugs in the first trimester of pregnancy and genital abnormalities in male and female foetuses. There are insufficient data to quantify the risk to exposed female foetuses, however some of these drugs induce mild virilisation of the external genitalia of the female foetuses. If a patient is exposed to **Meget**™ during the first four months of pregnancy or if she becomes pregnant whilst taking Megestrol, she should be apprised of the potential risks to the foetus. Women of child bearing potential should be advised to avoid becoming pregnant. Lactation: Because of the potential for adverse effects, nursing should be discontinued during treatment with Megestrol Acetate. Pediatric Use: Use in children safety and effectiveness in children have not been established.

OVERDOSAGE

No acute toxicological effects have resulted from studies involving Megestrol Acetate administered in dosages as high as 1600 mg/day for six months or more. Reports of overdose have also been received in the postmarketing setting. Signs and symptoms reported in the context of overdose included Diarrhoea, Nausea, Abdominal pain, shortness of breath, Cough, Unsteady gait, Listlessness, & Chest pain. There is no specific antidote for overdose with **Meget**™. In case of overdose, appropriate supportive measures should be taken.

STORAGE

Store below 30^0 C. Protect from light and moisture. Keep all medicine out of the reach of children.

HOW SUPPLIED

Meget™ 160 tablet: Each box contains 30 tablets in Alu-Alu blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH