PRODUCT MONOGRAPH

MEGESTROL

Megestrol Acetate Tablets USP

40 mg and 160 mg

PHARMACOLOGICAL CLASSIFICATION

Progestogen / Antineoplastic / Antianorexic / Anticachectic

Information for Patients

Patients should be advised to use MEGESTROL as directed and report any adverse reaction experiences to their physician. Women of childbearing potential should be advised to avoid becoming pregnant and should exercise adequate contraceptive control. If patients become pregnant while taking MEGESTROL, they should promptly notify their physician.

ADVERSE REACTIONS

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 and 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 (with or without hypercalcemia), 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.

Laboratory evidence of pituitary–adrenal axis abnormalities has been observed in patients treated with megestrol acetate. Although the significance of these laboratory findings has not been fully established, clinically apparent adrenal insufficiency has been reported to occur rarely in patients shortly after megestrol acetate was discontinued. Patients should be observed for clinical evidence of adrenocortical insufficiency when megestrol acetate is abruptly withdrawn.

In patients with advanced, non–endocrine–sensitive cancer who received doses of megestrol acetate up to 480 mg/day in a clinical trial for anorexia and weight loss, dyspnea, nausea, edema, pain, lethargy and diarrhea were observed commonly. Constipation and urinary frequency also have been reported in patients who received high doses of megestrol acetate in other clinical trials.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

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.