Megenox

Oral Suspension

Megestrol Acetate USP 40 mg/ ml

Composition
Each ml suspension contains 40 mg of Megestrol Acetate USP.

Pharmacology
Megestrol Acetate, a synthetic derivative of the steroid hormone, progesterone. The precise mechanism by which Megestrol Acetate produces effects in Anorexia and Cachexia is unknown at the present time. Several investigations have reported on the appetite enhancing property of Megestrol Acetate and it's possible use in Anorexia, Cachexia. Studies indicate that there is a statistically significant negative correlation between the level of pro-inflammatory cytokines such as IL1, IL6, TNF with various nutritional parameters and improvement in quality of life and weight gain.

Pharmacokinetics
Plasma concentrations of Megestrol Acetate are dependent, not only on the method used, but also on intestinal and hepatic inactivation of the drug, which may be affected by factors such as intestinal tract motility, intestinal bacteria, antibiotics administrated, body weight, diet, and liver function. The effect of food on the bioavailability of Megestrol Acetate oral suspension has not been evaluated.
The major route of drug elimination in human is urine. The mean elimination half life ranged from 20 to 50 hours in healthy subject.

Indications
Megestrol Acetate oral suspension is indicated for the treatment of Anorexia, Cachexia, or an unexplained, significant weight loss in patients with any advance diseases.

Dosage & administration
Route of administration : Oral.
The recommended adult initial dosage of Megestrol Acetate oral suspension is 800 mg/day (20 ml/day).

Contraindications
- History of hypersensitivity to Megestrol Acetate or any component of the formulation.
- Known or suspected pregnancy.

Precautions
Therapy with Megestrol Acetate oral suspension for weight loss should only be instituted after treatable causes of weight loss are sought and addressed. These treatable causes include possible malignancies, systemic infections, gastrointestinal disorders affecting absorption, endocrine disease and renal or psychiatric diseases. Effects on HIV viral replication have not been determined. Use with caution in patients with a history of thromboembolic disease.
Use in Diabetics: Exacerbation of pre-existing diabetes with increased insulin requirements has been reported in association with the use of Megestrol Acetate.

Side effects
Common side effects : Adverse events which occurred in at least 5% of patients in any arm of the two clinical efficacy trials and the open trial are listed below by treatment group. These adverse events are - diarrhea, impotence, rash, flatulence, hypertension, asthenia, insomnia, nausea, anaemia, fever, libido decreased, dyspepsia, hyperglycemia, headache, vomiting, pneumonia & urinary frequency.
Adverse events which occurred in 1% to 3% of all patients enrolled in the two clinical efficacy trials with at least one follow-up visit during the first 12 weeks of the study are listed below by body system.
• Body as a Whole: abdominal pain, chest pain, infection, candidiasis and sarcoma
• Cardiovascular System: cardiomyopathy and palpitation
• Digestive System: constipation, dry mouth, hepatomegaly & increased salivation
• Hemic and Lymphatic System: leukopenia
• Metabolic and Nutritional: LDH increased, edema and peripheral edema
• Nervous System: paresthesia, confusion, convulsion, depression, neuropathy, hypoesthesia and abnormal thinking
• Respiratory System: dyspnea, cough and lung disorder
• Skin and Appendages: alopecia, herpes, pruritus, vesiculobullous rash, sweating and skin disorder
• Urogenital System: albuminuria, urinary incontinence, urinary tract infection and gynecomastia.

Use in Pregnancy & Lactation
Pregnancy: There are no adequate and well-controlled studies in pregnant women. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant.
Lactation: Because of the potential for adverse effects on the newborn, nursing should be discontinued if Megestrol Acetate oral suspension is required.

Use in Children & Adolescents
Safety and effectiveness in pediatric patients have not been established.

Geriatric use
Clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. Megestrol Acetate is known to be substantially excreted by the kidney and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Drug Interactions
With medicine: Pharmacokinetic studies show that there are no significant alterations in pharmacokinetic parameters of Zidovudine or Rifabutin to warrant dosage adjustment when Megestrol Acetate is administered with these drugs. The effects of Zidovudine or Rifabutin on the pharmacokinetics of Megestrol Acetate were not studied. Megestrol Acetate may interact with Warfarin and increase International Normalized Ratio (INR).

Overdose
No serious unexpected side effects have resulted from studies involving Megestrol Acetate oral suspension administered in dosages as high as 1200 mg/day.

Storage
Store below 30^0 C and dry place, protected from light.
Keep all medicines out of reach of children.

Packaging
Each bottle contains 100 ml oral suspension & a measuring cup.

* Further information is available on request.

07 0000

Manufactured by:
The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness