Megestol Oral Suspension

Megestrol Acetate USP 40 mg/ml

Composition
Megestol Oral Suspension: Each ml suspension contains 40 mg of Megestrol Acetate USP.

Description
Megestrol Acetate is a synthetic derivative of the naturally occurring steroid hormone, Progesterone.

Mode of Action
Several investigators have reported on the appetite enhancing property of Megestrol Acetate and its possible use in anorexia, cachexia. The precise mechanism by which Megestrol Acetate produces effects in anorexia and cachexia is unknown at the present time but some studies indicate there is a statistically significant negative correlation between the level of pro-inflammatory cytokines such as IL_1 IL_6,TNF with various nutritional parameters and improvement in quality of life and wieght 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 administered, 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.

Indication
Megestol Oral Suspension is indicated for the treatment of anorexia, cachexia.

Dosage and Administration
The recommended adult initial dosage of **Megestol Oral Suspension** is 800 mg/day (20 ml/day).

Precautions
General therapy with Megestrol Acetate for weight loss should only be instituted after treatable causes of weight loss are required 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 have been reported in association with the use of Megestrol Acetate.

Pregnancy
Pregnancy Category X. 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.

Nursing Mother
Because of the potential for adverse effects on the newborn, nursing should be discontinued if Megestrol Acetate is required.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

Geriatric Use
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.

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 should be considered by the physician when prescribing Megestrol Acetate. Those 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, oedema and peripheral oedema
- *Nervous System:* paresthesia, confusion, convulsion, depression, neuropathy, hypesthesia 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

Contraindication

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

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

Drug interactions
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.

Storage
Store at 20^0 to 25^0C (68° to 77^0F). Protect from heat. Shake well immediately before use.

Packaging
Megestol Oral Suspension: Each bottle contains 100 ml suspension.

Manufactured by :

ZISKA PHARMA

Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh