Apit
Suspension

DRUG INTERNATIONAL LTD.

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

Pharmacology : The precise mechanism by which Megestrol Acetate produces effects in anorexia and cachexia is unknown at the present time. Absorption of it is well. Metabolism is primarily hepatic and the major route of elimination is human is urine. After administration of 4 to 90 mg in human, the urinary excretion within 10 days ranged from 56.5% to 78.9% (mean 66.4%) and fecal excretion from 7.7% to 30.0% (mean 19.8%). Elimination half-life ranges from 20 to 50 hours.

Indications : It is indicated for the treatment of anorexia, cachexia, or an unexplained, significant weight loss in patients with a diagnosis of acquired immunedeficiency syndrome (AIDs) & cancer.

Dosage and administration : The recommended adult initial dosage is 800 mg/day (20 ml/day). The bottle should be shaken well before use. Or, as directed by the registered physician.

Contraindication : It is contraindicated in patients who are hypersensitive to any component of this product.

Precautions : Therapy with Megestrol 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. It should be used with caution in patients with a history of thromboembolic disease.

Side effects : **Body as a Whole:** abdominal pain, chest pain, infection, moniliasis and sarcoma.

Cardiovascular System: cardiomyopathy and palpitation. **Digestive System:** constipation, dry mouth, hepatomegaly, increased salivation and oral moniliasis. **Hemic and Lymphatic System:** leucopenia. **Metabolic and Nutritional:** LDH increased, edema and peripheral edema. **Nervous System**: paresthesia, confusion, convulsion, depression, neuropathy, hypesthesia and abnormal thinking.

Respiratory System: dyspnea, cough, pharyngitis and lung disorder. **Skin and Appendages:** alopecia, herpes, pruritus, vesiculobullous rash, sweating and skin disorder. **Special Senses:** amblyopia. **Urogenital System:** albuminuria, urinary incontinence, urinary tract infection and gynecomastia.

Use in pregnancy and lactation : Pregnancy category X. There are no adequate and well-controlled studies of Megestrol administration in pregnant Women. It is a progesterone derivative, which may induce vaginal bleeding in women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Because of the potential for adverse effects on the newborn, nursing should be discontinued if Megestrol oral suspension is required.

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

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. Megestrol Acetate may interact with Warfarin and increase international Normalized Ratio (INR) so patients should be closely monitored.

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

Storage : Store below 30°C in a dry place and keep out of reach of children.

Packing : Each bottle contains 100 ml oral suspension.