Apetiz

Megestrol Acetate USP

Composition
Apetiz Tablet: Each film coated tablet contains Megestrol Acetate USP 160 mg.
Apetiz Oral Suspension: 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 Megestrol Acetate is well. Metabolism is primarily hepatic and the major route of drug elimination in human is urine. After administration of 4 to 90 mg Megestrol Acetate in human, the urinary excretion within 10 days ranged from 56.5% to 78.4% (mean 66.4%) and fecal excretion ranged from 7.7% to 30.3% (mean 19.8%). The elimination half-life of Megestrol Acetate ranges from 20 to 50 hours.

Indications
Apetiz is indicated for the treatment of anorexia, cachexia, or an unexplained significant weight loss in patients diagnosis with Acquired Immunodeficiency Syndrome (AIDS). **Apetiz** is also indicated for the palliative treatment of advanced carcinoma of the breast (i.e. recurrent, inoperable or metastatic diseases). It should not be used in lieu of currently accepted procedures such as surgery, radiation or chemotherapy.

Dosage & Administration
Anorexia-cachexia syndrome: The recommended dose of **Apetiz** is 400 to 800 mg/day (10 to 20 ml/day) for at least two months and could be taken without regard to meal.
Breast cancer: The recommended dose of **Apetiz** is 160 mg/day in single or divided doses.

Shake the bottle well before use.

Contraindications
History of hypersensitivity to Megestrol Acetate or any component of the formulation and in case of known or suspected pregnancy.

Warning & Precaution
History of thromboembolic disease. Monitor for signs/symptoms of adrenal insufficiency; consider empiric therapy if occurs. Diabetes, renal impairment, elderly, fetal toxicity, obtain (-) pregnancy test prior to initiation. Advise females of reproductive potential to use effective contraception during therapy and for nursing mothers it is not recommended.

Side Effects
Some common adverse events which occurred in at least 5% of patients are diarrhea, impotence, rash, flatulence, hypertension, asthenia, insomnia, nausea, anemia, fever, decreased libido, dyspepsia, hyperglycemia, headache, pain, vomiting, pneumonia & urinary frequency. Some other adverse events also occurred in 1% to 3% of all patients are abdominal pain, chest pain, infection, moniliasis and sarcoma, cardiomyopathy and palpitation, constipation, dry mouth, hepatomegaly, increased salivation and oral moniliasis, leukopenia, increased LDH, edema & peripheral edema, paresthesia, confusion, convulsion, depression, neuropathy, hyperesthesia & abnormal thinking, dyspnea, cough, pharyngitis & lung disorder, alopecia, herpes, pruritus, vesiculobullous rash, sweating and skin disorder, amblyopia, albuminuria, urinary incontinence, urinary tract infection and gynecomastia. A rarely encountered side effect of prolonged administration of Megestrol Acetate is urticaria.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Common			
Edema (caused by excess fluid)		✓	
Very Rare			
Adrenal insufficiency (abdominal pain, nausea, vomiting, dizziness, weakness, fatigue, low blood pressure and kidney failure.)			✓
Pulmonary embolism (sudden chest pain, shortness of breath, cough, fatigue, and heart palpitations)			✓
Tumor Flare (temporary worsening of tumor symptoms, such as pain, redness, or tumor size)		✓	
Vaginal bleeding	✓		
Unknown			
Carpal tunnel syndrome (numbness and tingling in the hand and arm)	✓		
Cushing's syndrome (round and red face, high blood pressure, abdomen obesity with thin arms and legs, red stretch marks, a fat lump between the shoulders, weak muscles, weak bones, acne, and fragile skin that heals poorly. Women may have more hair and irregular menstruation)		✓	
Dyspnea (difficulty breathing, shortness of breath)	✓		
Heart failure			✓
High blood pressure		✓	
Loss of hearing		✓	
Osteoporosis/osteopenia (weak and brittle bones)		✓	
New or worsening diabetes or hyperglycemia (unusual thirst, hunger, frequent urination, fatigue, or weight gain or loss)		✓	
Thrombophlebitis (inflammation of veins)		✓	

Please notify your doctor if any adverse effect continues or becomes bothersome.

Use in Pregnancy & Lactation
No adequate animal teratology information is available at clinically relevant doses. So, it should be avoided in pregnancy and lactation.

Use in Children & Adolescents
Although safety and effectiveness of Megestrol Acetate in pediatric patients have not been established, some clinical trials are found to use it safely in children of 8 months to 10 years at a median daily dose of 10 mg/kg body weight (range from 3.3 to 12 mg/kg body weight/day).

Geriatric Use
In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range.

Drug Interaction
Pharmacokinetic studies show that there is no significant alteration in pharmacokinetic parameters of Zidovudine or Rifabutin to warrant dosage adjustment when Megestrol Acetate is administered with these drugs.

Overdose
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.

Storage
Apetiz Tablet: Store within 30°C. Protect from light.
Apetiz Oral Suspension: Store within 25°C, protect from light and moisture. Keep away from the reach of children.

Packing
Apetiz Tablet: Each box contains 10/30 tablets in alu-alu blister pack.
Apetiz Oral Suspension: Each bottle contains 100 ml oral suspension.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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