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hovid

hovid-Megestrol

VIMEGxx-05

Oral Suspension 40 mg/ml

DESCRIPTION
hovid-Megestrol Oral Suspension 40 mg/ml contains megestrol acetate, a synthetic derivative of the naturally occurring steroid hormone, progesterone. It is a white to light yellow suspension.

COMPOSITION
Each ml contains megestrol acetate 40 mg.

Each ml contains sodium benzoate 2 mg as preservatives.

PHARMACODYNAMICS
Several investigators have reported on the appetite enhancing property of megestrol acetate and its possible use in cachexia. The precise mechanism by which megestrol acetate produces effects in anorexia and cachexia is unknown at the present time.

PHARMACOKINETICS
Absorption and Distribution
Megestrol acetate plasma concentrations are dependent on the 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.

Metabolism and Excretion
The major route of drug elimination of megestrol acetate in humans is urine. Metabolites have accounted for only 5% to 8% of an administered dose of megestrol acetate. The administered dose is usually excreted in the urine (approx. 66%) and faeces (approx. 20%).

The effect of food on the bioavailability of hovid-Megestrol Oral Suspension 40 mg/ml is unknown.

INDICATION
hovid-Megestrol Oral Suspension 40 mg/ml is indicated in male and female patients for the treatment of anorexia or weight loss secondary to cancer or acquired immune deficiency syndrome.

CONTRAINDICATIONS
History of hypersensitivity to megestrol acetate or any component of the formulation. Known or suspected pregnancy.

WARNING AND PRECAUTIONS
Warnings
Megestrol acetate may cause fetal harm when administered to a pregnant woman. 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 (receiving) 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.

Megestrol acetate is not intended for prophylactic use to avoid weight loss.

The glucocorticoid activity of hovid-Megestrol Oral Suspension 40 mg/ml has not been fully evaluated. Clinical cases of new onset diabetes mellitus, exacerbation of pre-existing diabetes mellitus, and overt Cushing's syndrome have been reported in association with the chronic use of megestrol acetate. In addition, clinical cases of adrenal insufficiency have been observed in patients receiving or being withdrawn from chronic megestrol acetate therapy in the stressed and non-stressed state. Furthermore, adrenocorticotropin (ACTH) stimulation testing has revealed the frequent occurrence of asymptomatic pituitary-adrenal suppression in patients treated with chronic megestrol acetate therapy. Therefore, the possibility of adrenal insufficiency should be considered in any patient receiving or being withdrawn from chronic megestrol acetate therapy who presents with symptoms and/or signs suggestive of hypoadrenalism (e.g., hypotension, nausea, vomiting, dizziness, or weakness) in either the stressed or non-stressed state. Laboratory evaluation for adrenal insufficiency and consideration of replacement or stress doses of a rapidly acting glucocorticoid are strongly recommended in such patients. Failure to recognize inhibition of the hypothalamic-pituitary-adrenal axis may result in death. Finally, in patients who are receiving or being withdrawn from chronic megestrol acetate therapy, consideration should be given to the use of empiric therapy with stress doses of a rapidly acting glucocorticoid during stress or serious intercurrent illness (e.g., surgery, infection).

Precautions
General
Therapy with hovid-Megestrol Oral Suspension 40 mg/ml 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 have been reported in association with the use of megestrol acetate.

Information for Patients
Patients using megestrol acetate should receive the following instructions:
1. This medication is to be used as directed by the physician.
2. Report any adverse reaction experiences while taking this medication.
3. Use contraception while taking this medication if you are a woman capable of becoming pregnant.
4. Notify your physician if you become pregnant while taking this medication.

Impairment of Fertility
In a perinatal/postnatal toxicity studies, the reproductive capability of male offspring of megestrol acetate-treated females was impaired in a low dose. Similar results were obtained in dogs. Pregnant rats treated with megestrol acetate showed a reduction in fetal weight and number of live births, and feminization of male fetuses. No toxicity data are currently available on male reproduction (spermatogenesis).

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hovid-Megestrol Oral Suspension 40 mg/ml

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

Geriatric Use
Clinical studies of megestrol acetate in the treatment of anorexia, cachexia, or an unexplained, significant weight loss in patients with AIDS did not include sufficient numbers of patients aged 65 years and older to determine whether they respond differently than younger patients. Other reported 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.

PREGNANCY AND LACTATION

Pregnancy
Pregnancy Category X
No adequate animal teratology information is available at clinically relevant doses.

Lactation
Because of the potential for adverse effects on the newborn, nursing should be discontinued if hovid-Megestrol Oral Suspension 40 mg/ml is required.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

There are no known effects of megestrol acetate on the ability to drive or operate machinery.

DRUG INTERACTIONS

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.

MAIN SIDE/ADVERSE EFFECTS

These adverse events should be considered by the physician when prescribing hovid-Megestrol Oral Suspension 40 mg/ml.

Body as a Whole
Abdominal pain, chest pain, infection, moniliasi, sarcoma

Cardiovascular System
Cardiomyopathy, palpitation

Digestive System
Constipation, dry mouth, hepatomegaly, increased salivation and oral moniliasis

Hemic and Lymphatic System
Leukopenia

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

OVERDOSE AND TREATMENT

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

DOSAGE AND ADMINISTRATION

Anorexia or weight loss
400 - 800 mg given as a single daily dose. Shake the suspension container well before using. A plastic dosage cup is provided for convenience.

At least two months of continuous treatment is considered an adequate period for determining the efficacy of megestrol acetate.

For oral use only.

Storage	: Store below 30°C.
Presentation/ Packing	: 120 ml HDPE bottle with 20 ml polypropylene measuring cup.
Product Registration Holder	: HOVID Berhad., 121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar), 30010 Ipoh, Perak, Malaysia.
Manufactured by	: Winston Medical Supply Co., Ltd., No.117, Ren'ai St., Yongkang Dist., Tainan City, Taiwan, R.O.C
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