Merol (Megestrol Acetate) Innerleaf design Revise

Pantone Metallic Coated 8483 C & 185 C

W- 120 mm, X H- 228 mm

Merol-A™

Megestrol Acetate USP

Jenphar Bangladesh | جنفار بنغلاديش

Composition:

Merol-A™ 160: Each film coated tablet contains Megestrol Acetate USP 160 mg.

Pharmacology:

Megestrol Acetate is a synthetic, antineoplastic and progestational drug. Its molecular weight is 384.51. The molecular formula is $C_{24}H_{32}O_4$. The anti-tumour action of Megestrol Acetate on carcinoma of the breast is unclear. However, it is known to compete for progesterone, androgen and glucocorticoid receptors and effect pituitary functions.

Indication:

Megestrol Acetate is indicated for the palliative treatment of advanced carcinoma of the breast or endometrium (i.e., recurrent, inoperable, or metastatic disease). It should not be used in lieu of currently accepted procedures such as surgery, radiation or chemotherapy. It is also indicated for the treatment of anorexia, cachexia or weight loss secondary to metastatic cancer.

Dose & administration:

Breast Cancer: 160 mg/day (160 mg taken once daily). At least two months of continuous treatment is considered an adequate period for determining the efficacy of megestrols. Best results are obtained in previously untreated receptor-positive cases that are more than five years post-menopausal (approximately 40% response rate). In patients with less favourable characteristics the response rate could be 15% or less.
Endometrial Carcinoma: 40 – 320 mg/day in divided doses (40 – 80 mg one to four times daily or one to two 160mg tablets daily). At least two months of continuous treatment is considered an adequate period for determining the efficacy of megestrol.
Cachexia: 400 – 800 mg/day

Contra-indication:

Megestrol Acetate is contraindicated in patients with a history of hypersensitivity to megestrol acetate or any component of the formulation.

Warning and precaution:

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.

Side Effects:

- *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

Use in Specific Populations:

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.
Pregnancy: Category D
Breast-feeding: Very small amounts (approximately 0.1%) are excreted in mother's milk. It is however, not known whether these amounts exert any harmful effects on the newborn. Because of the potential for adverse effects on the newborn, nursing should be discontinued during treatment.

Drug Interaction:

There is no data available

Overdose:

No serious side effects have resulted from studies involving megestrol acetate administered in dosages as high as 1600 mg/day for 6 months or more. No acute toxicological effects have been recognized in these studies. Oral administration of large single doses of megestrol acetate (5g/kg) did not produce toxic effects in mice. Due to low solubility of megestrol acetate it is unlikely that dialysis would be an effective means of treating over dosage.

Storage:

Store at 25°C, protect from light. Keep out of the reach of children.

Packing:

Merol-A™ 160: Each box contains 3X8's tablets in Alu-Alu blister pack.

Ver.: 01

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Manufactured for

Jenphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.

by **Techno Drugs Ltd.**

Satirpara, Narsingdi, Bangladesh