

Megpro™ 40 mg 160 mg

Magestrol Acetate Tablets

Proactively Stimulate Appetite

Product Description:

Megpro 160 mg: Each tablet contains Megestrol Acetate 160 mg

Megpro 40 mg: Each tablet contains Megestrol Acetate 40 mg

Description: Megestrol acetate is a white to creamy–white, odourless, crystalline powder. Megestrol acetate is insoluble in water, sparingly soluble in alcohol, slightly soluble in ether and in fixed oils. It is soluble in acetone and very soluble in chloroform. Megestrol acetate is unstable under aqueous conditions at pH 7 or above. It has a melting point of 213 – 219°C.

Composition: MEGPRO is available in 40 and 160 mg tablet form

Pharmacokinetics:

Absorption: Megestrol is well absorbed. Time to peak concentrations is from 1 to 3 hours for megestrol acetate tablets. The onset of the action takes 3 to 4 weeks for weight gain.

Metabolism: Megestrol is metabolized by UDP-glucuronosyltransferases (UGTs) and CYP3A4 is an important enzyme found in the liver.

Excretion: Urinary excretion is the major route; urinary excretion varies between 56.5% to 78.4% (mean 66.4%). Fecal excretion varies from 7.7% to 30.3% (mean 19.8%).

DOSAGE: For the following indications, at least two months of continuous treatment is considered an adequate period for determining the efficacy of MEGPRO (megestrol acetate) tablets.

The 40 mg oral tablet is usually prescribed four times a day as a starting dosage and 160 mg/day taken once daily.

Literature has indicated that dosages can vary from 100 mg to 1600 mg/day for appetite stimulation. Megestrol demonstrates a positive dose-response effect for improving appetite. Megestrol is typically recommended for a minimum of six weeks.

ADMINISTRATION: Megpro: Taken with or without food.

INDICATIONS AND CLINICAL USE:

Megpro is indicated for the treatment of anorexia, cachexia, or an unexplained, significant weight loss in patients.

CONTRAINDICATIONS: Megpro (megestrol acetate) is contraindicated in those people who are sensitive to megestrol acetate or any ingredients in the dosage form. It should not be used in pregnancy.

SYMPTOMS AND TREATMENT OF OVERDOSAGE: Usual safety measures as with the overdose of any medication should be instituted. However, 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.

SIDE EFFECTS:

The most common side effect of Megestrol is weight gain, with an incidence of 15 to 70% at the high dosages. Other side effects include vaginal bleeding (7–8%), nausea (7%), and edema (5%), as well as others such as dizziness and shortness of breath.

Drug Interaction: Various drug interactions can be divided into severe, serious, and moderate interactions. Severe interactions have occurred with an anti-arrhythmic drug named dofetilide. Serious interactions causing harmful effects have been described in immuno-modulating drugs like filgotinib and some selected immunosuppressive drugs like leflunomide. The most common moderate interactions with some risks are coumarin anticoagulants like warfarin and dicumarol.³⁶ Various antineoplastic drugs like bleomycin, capecitabine, carboplatin, cisplatin, etc., have minor interactions with megestrol acetate. There are no food interactions documented with this drug.

Reference:

1. House L, Seminerio MJ, Mirkov S, Ramirez J, Skor M, Sachleben JR, Isikbay M, Singhal H, Greene GL, Vander Griend D, Conzen SD, Ratain MJ, Metabolism of megestrol acetate in vitro and the role of oxidative metabolites. *Xenobiotica; the fate of foreign compounds in biological systems*. 2018 Oct [PubMed PMID: 29050522]
2. Megace® OS (Megestrol acetate, USP) Oral Suspension. Bristol–Myers Squibb Pharmaceutical Group, Montreal, Canada. Preparation Date: October 25, 2005, Control Number: 101903.
3. Richard R. Barakat; Maurie Markman; Marcus Randall (2009). *Principles and Practice of Gynecologic Oncology*. Lippincott Williams & Wilkins. pp. 447–. ISBN 978-0-7817-7845-9.
4. Canetta R, Florentine S, Hunter H, Lenaz L (September 1983). "Megestrol acetate". *Cancer Treat. Rev.* 10 (3): 141–57. doi:10.1016/0305-7372(83)90029-4. PMID 6352021.
5. Willemsse PH, van der Ploeg E, Sleijfer DT, Tjabbes T, van Veelen H (March 1990). "A randomized comparison of megestrol acetate (MA) and medroxyprogesterone acetate (MPA) in patients with advanced breast cancer". *Eur. J. Cancer.* 26 (3): 337–43. doi:10.1016/0277-5379(90)90231-h. PMID 2141491.
6. Go.drugbank.com. Drug interactions with Megestrol acetate [updated 20 Feb 2020]. Accessed November 23, 2021 at: <https://go.drugbank.com/drugs/DB00351>