Only for the use of Medical Professionals

Ornical®

Orlistat

Description

Ornical® is a preparation of Orlistat which is a potent, specific & long acting inhibitor of gastrointestinal lipases that acts by inhibiting the absorption of dietary fats. It exerts its therapeutic activity in the lumen of the stomach and small intestine by forming a covalent bond with the active serine residue site of gastric and pancreatic lipase. The inactivated enzymes are thus unavailable to hydrolyze dietary fat in the form of triglycerides into absorbable free fatty acids and monoglycerides. As undigested triglycerides are not absorbed, the resulting caloric deficit may have a positive effect on weight control.

Indications & usage

Ornical® is indicated for the treatment of weight control, including weight loss, weight maintenance and prevention of weight regain in adults with an initial body mass index (BMI) of 30 or more. **Ornical®** should be used in conjunction with a low fat, calorie controlled diet.

Dosage & administration

Adult over 12 years

The recommended dose of **Ornical®** is one 120 mg capsule three times a day with each main meal (immediate before, during or up to one hour after the meal) ; continue treatment beyond 12 weeks only if weight loss since start of treatment exceeds 5% (target for initial weight loss may be lower in patients with type 2 diabetes). The patient should be on a nutritionally balanced, mildly hypocaloric diet that contains approximately 30% of calories from fat. It is recommended that the diet should be rich in fruit and vegetables. The daily intake of fat, carbohydrate and protein should be distributed over three main meals.

Children: Safety and efficacy have not been established in children younger than 12 years.

Elderly (>65 years old) and patients with hepatic and renal impairment: The effect of Orlistat in elderly patients and patients with hepatic and renal impairment has not been studied.

Pregnancy & lactation

Pregnancy

Orlistat is Pregnancy Category X drug. Orlistat is contraindicated during pregnancy, because weight loss offers no potential benefit to a pregnant woman and may result in fetal harm. A minimum weight gain, and no weight loss, is currently recommended for all pregnant women, including those who are already overweight or obese, due to the obligatory weight gain that occurs in maternal tissues during pregnancy. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard of maternal weight loss to the fetus.

Lactation

It is not known if Orlistat is present in human milk. Caution should be exercised when Orlistat is administered to a nursing woman.

Side effects

Most common side effects of Orlistat are oily spotting, flatus with discharge, fecal urgency fatty/oily stool, oily evacuation, increased defecation and fecal incontinence.

Contraindications
Orlistat is contraindicated in patients with known hypersensitivity to Orlistat or to any component of this product, chronic malabsorption syndrome and cholestasis.

Precautions
Patients should be advised to adhere to the dietary recommendations they are given. Patients should be strongly encouraged to take a multivitamin supplement that contains fat-soluble vitamins to ensure adequate nutrition because Orlistat has been shown to reduce the absorption of some fat-soluble vitamins and beta-carotene. In addition, the levels of vitamin D and beta-carotene may be low in obese patients compared with nonobese subjects. The supplement should be taken once a day at least 2 hours before or after the administration of Orlistat, such as at bedtime. Some patients may develop increased levels of urinary oxalate following treatment with Orlistat. Caution should be exercised when prescribing Orlistat to patients with a history of hyperoxaluria or calcium oxalate nephrolithiasis. Weight-loss induction by Orlistat may be accompanied by improved metabolic control in diabetics, which might require a reduction in dose of oral hypoglycemic medication (eg, sulfonylureas, metformin) or insulin. Therefore antidiabetic medicinal product treatment may have to be closely monitored when taking Orlistat. Substantial weight loss can increase the risk of cholelithiasis.

Drug interactions
Reduction in cyclosporine plasma levels when Orlistat was coadministered with cyclosporine. Orlistat inhibited absorption of a vitamin E acetate supplement. The effect of Orlistat on the absorption of supplemental vitamin D, vitamin A, and nutritionally-derived vitamin K is not known. Hypothyroidism has been reported in patients treated concomitantly with Orlistat and levothyroxine. Patients treated concomitantly with Orlistat and levothyroxine should be monitored for changes in thyroid function. Administer levothyroxine and Orlistat at least 4 hours apart. Vitamin K absorption may be decreased with Orlistat. Patients on chronic stable doses of warfarin who are prescribed Orlistat should be monitored closely for changes in coagulation parameters. Convulsions have been reported in patients treated concomitantly with Orlistat and antiepileptic drugs. Patients should be monitored for possible changes in the frequency and/or severity of convulsions.

Over dosage
Single doses of 800 mg Orlistat and multiple doses of up to 400 mg three times a day for 15 days have been studied in normal weight and obese subjects without significant adverse findings. Should a significant overdose of Orlistat occur, it is recommended that the patient be observed for 24 hours. Based on human and animal studies, systemic effects attributable to the lipase-inhibiting properties of Orlistat should be rapidly reversible.

Pharmaceutical precautions
Store in a cool & dry place. Protect from light. Keep out of the reach of children.

Presentation
Ornical® capsule: Each capsule contains Orlistat USP 120mg

Package quantities
Ornical® capsule: Carton of 20 capsules in blister pack

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