

Orlistat-Sigma *Capsules*



Generic name:

Orlistat

Composition:

Each capsule contains:

Active ingredient:

Orlistat 120 mg

Inactive ingredients:

Avicel PH 101, Sodium starch glycolate, Sodium lauryl sulphate, Povidone and Talc

Pharmaceutical form:

Capsules

Pharmacological actions:

Orlistat-Sigma is a reversible inhibitor of lipases. 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 lipases. 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 has a positive effect on weight control.

Pharmacokinetics:

Orlistat-Sigma is minimally absorbed after oral doses

Indications:

Orlistat-Sigma is indicated for:

-Management weight loss for obese adult and adolescents 12 years old or older.

-Weight maintenance

-To prevent regaining weight previously lost.

-Overweight patients with an initial body mass index (BMI) $\geq 30 \text{ kg/m}^2$ or $\geq 27 \text{ kg/m}^2$ if other risk factors are present (e.g: hypertension, diabetes and dyslipidemia).

Dosage and Administration:

The recommended dose of Orlistat-Sigma is one 120 mg capsule three times a day with each main meal containing fat (during or up to 1 hour after the meal).

The patient should be on a nutritionally balanced, reduced-calorie diet that contains approximately 30% of calories from fat.

Pediatric Use:

The safety and efficacy of Orlistat-Sigma have not been established in children below 12 years old.

Contraindications:

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

Side effects:

A gastrointestinal (GIT) effect: (steatorrhea) liquid or oily stool lasts for few weeks and minimized by reduced fat intake.

Drug Interactions:

-Orlistat-Sigma may reduce the plasma concentration of cyclosporine. So, cyclosporine should be administered two hours after or before Orlistat-Sigma.

-Orlistat-Sigma may reduce the absorption of fat-soluble vitamins.

-Avoid use with acarbose.

Pregnancy and lactation:

Orlistat-Sigma should not be taken by nursing and pregnant women (Category B).

Precautions and warnings:

Caution should be taken with patients with a history of hyperoxaluria or calcium oxalate nephrolithiasis. Absorption of fat-soluble vitamins and Beta-carotene is inhibited by Orlistat-Sigma, so patients should be counseled to take a multivitamin containing fat-soluble vitamins to ensure adequate nutrition.

Package and storage:

Store at controlled room temperature 15°C - 30°C .

A box containing 1 blister of 10 capsules.

A box containing 2 blisters, each of 10 capsules.

A box containing 3 blisters, each of 10 capsules.