

OrlistatTM

CAPSULES

Dosage Form

Hard gelatin capsules

Composition

Each capsule contains:

Orlistat 120 mg

Approved colours used for capsule shells.

Pharmacological effects

ORLIGAL is a potent, specific and reversible long-acting inhibitor of gastrointestinal lipases. It exerts its therapeutic activity in the lumen of the stomach and small intestine by forming a covalent bond with the serine residue of the active site of gastric and pancreatic lipases. The inactivated enzyme is thus unable to hydrolyse 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 the weight control.

Indications

ORLIGAL is for 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.

ORLIGAL should be used in conjunction with a low fat, calorie controlled diet.

Dosage

Adults

The recommended dose of **ORLIGAL** is one 120 mg capsule three times a day with each main meal (during or up to one hour after the meal).

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 in fruit and vegetables. The daily intake of fat, carbohydrate and protein should be distributed over three main meals. No dose adjustment is necessary for the geriatric patient.

Contraindications

ORLIGAL is contraindicated in patients with chronic malabsorption syndrome, cholestasis and in patients with known hypersensitivity to orlistat or any of the components contained in the medicinal product.

Warnings and Precautions

The majority of patients in long-term studies of up to four years of treatment had vitamin A, D, E, and K and beta-carotene levels within normal range. In order to ensure adequate nutrition, the use of a multivitamin supplement should be considered.

The possibility of experiencing gastrointestinal events may increase when **ORLIGAL** is taken with a diet high in fat (e.g. in a 2000 kcal/day diet, >30% of calories from fat equates to > 67 g of fat). The daily intake of fat should be distributed over three main meals. If **ORLIGAL** is taken with any one meal very high in fat, the possibility of gastrointestinal effects may increase. If a meal is missed, the dose of **ORLIGAL** may be omitted.

Weight loss induced by **ORLIGAL** is accompanied by improved metabolic control in type 2 diabetics which might allow or require reduction in the dose of hypoglycaemic medication (e.g. sulfonylureas).

A reduction in cyclosporin plasma levels has been observed when **ORLIGAL** is co-administered. Therefore it is recommended to monitor more frequently than usual the cyclosporin plasma levels when **ORLIGAL** is co-administered.

Coagulation parameters should be monitored in patients treated with concomitant oral anticoagulants.

In a PK study, oral administration of amiodarone during orlistat treatment demonstrated a 25-30% reduction in the systemic exposure to amiodarone and desethylamiodarone. Due to the complex pharmacokinetics of amiodarone, the clinical effect of this is unclear. The effect of commencing orlistat treatment in patients on stable amiodarone therapy has not been studied. A potential reduced therapeutic effect of amiodarone is possible.

Side effect and adverse reactions

Commonly observed events are oily spotting, flatus with discharge, faecal urgency, fatty/oil stool, oily evacuation, increased defaecation and faecal incontinence. The incidence of these increases the higher the fat content of the diet.

Drug interactions

Decreases in the absorption of vitamin D, E and B-carotene have been observed when co-administered with **ORLIGAL**. If a multivitamin supplement is recommended, it should be taken at least two hours after the administration of **ORLIGAL** or at bedtime.

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Pack

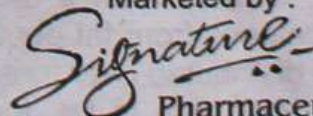
Blister pack of 4 X 21 capsules.

Storage

Store in cool, dry & dark place.

Manufactured in India by
Hab Pharmaceuticals & Research Ltd.,
10, Pharma City,
Sidcul, Selaqui,
Dehradun - 248 197.
Email : info@habpharma.in

Marketed by :



Pharmaceuticals Ltd.

Mumbai - 400 002.