

^{Rx} ORLISTAT CAPSULES USP

SLIM TRIM

ACTIVE CAPSULES

Dosage Form

Hard gelatin capsules

Composition

Slim Trim Active Capsules 60mg

Each hard gelatin capsule contains Orlistat USP 60mg

Slim Trim Active Capsules 120mg

Each hard gelatin capsule contains Orlistat USP 120mg

Approved colours used for capsule shells.

Pharmacological effects

Slim Trim Active is a potent, specific and reversible ling-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

Slim Trim Active 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.

Slim Trim Active should be used in conjunction with a low fat, calorie controlled diet.

Dosage

Adults

The recommended dose of Slim Trim Active is one 60 mg capsule three times a day with each main meal (during or up to one hour after the meal).

The patient should be on one nutritionally balanced, mildly hypo caloric 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 products.

Contraindications

Slim Trim Active 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 products

Warnings and precautions

The majority of patients with in long-term studies of up to four year 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 Slim Trim Active 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 Slim Trim Active 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 Slim Trim Active

may be omitted.

Weight loss induced by **Slim Trim Active** is accompanied by improved metabolic control in type 2 diabetics which might allow or require reduction in the dose of hypoglycemic medication (e.g. sulfonylurea).

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

Coagulation parameters should be monitored in patients treated with con-comitant 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 effects 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 only spotting, flatus with discharge faecal urgency, fatty/oil stool, only evacuation, increased defecation 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 **Slim Trim Active**. If a multivitamin supplement is recommended, it should be taken at least two hours after the administration of **Slim Trim Active** or at bedtime.

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Pack

Blister pack of 3x10 capsules.

Storage

Store below 25° C, Protected from light and moisture.



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