

AXCEL ORLISTAT TABLET

Orlistat (60mg, 120mg)

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What Axcel Orlistat Tablet is used for

Axcel Orlistat Tablet is indicated, in conjunction with a low calorie intake diet for the treatment of obesity (BMI ≥ 30 kg/m²) and overweight (BMI ≥ 28 kg/ m²), including people with risk factors associated with obesity. Axcel Orlistat Tablet is effective in weight loss, weight maintenance and prevention of weight regains. Treatment with Axcel Orlistat Tablet results in an improvement of risk factors and comorbidities (simultaneous presence of two chronic diseases) associated with obesity, including high blood cholesterol, high blood sugar, impaired sugar tolerance, high blood insulin, high blood pressure and in a reduction of abdominal fat.

How Axcel Orlistat Tablet works

Orlistat prevents the absorption of fat from food diet and hence, reduce the intake of calories.

Before you use Axcel Orlistat Tablet

When you must not use it

Do not take Axcel Orlistat Tablet if:

- You are allergic or hypersensitive to orlistat or any ingredients of this medication.
- You have chronic malabsorption syndrome (inability to absorb food) or cholestasis (decrease in bile flow from the liver).

Before you start to use it

Tell your doctor if:

- You are pregnant or breastfeeding.

Taking other medicines

You should tell your doctor if you are taking the following medicine as it may interact with your Axcel Orlistat Tablet:

- Warfarin or other anticoagulants (used to thin the blood)
- Cyclosporin (used to prevent rejection of organ transplant)
- Amiodarone or desethylamiodarone (used to treat irregular heartbeat)

How to use Axcel Orlistat Tablet

How much to use

For oral administration only.

The recommended dose of Axcel Orlistat Tablet is 120mg with each meal (during or up to one hour after the meal). If a meal is missed or contains no fat, the dose may be omitted. You should be on a nutritionally balanced, mildly low calorie intake diet that contains approximately 30% of calories from fat. The daily intake of fat, carbohydrate and proteins should be distributed over three main meals. Doses above 120mg three times daily have not been shown to provide additional benefit.

Special Dosage Instruction

There is no dosage recommendation for people with liver and/or kidney problems and children below 12 years old.

When to use it

Your doctor will decide when it is appropriate for you to take Axcel Orlistat Tablet according to the type of condition you have.

How long to use it

- Take this medicine as stated in the leaflet without exceeding the dosage.
- Follow any recommendations and advices from your doctor or pharmacist.

If you forget to use it

- Do not double up the dosage as Axcel Orlistat Tablet may give you unacceptable side effects.

If you use too much (overdose)

You must inform your doctor immediately if you have taken too much Axcel Orlistat Tablet.

While you are using it

Things you must do

- Discuss with your doctor or pharmacist the dos' and don'ts' while taking this medicine.
- Tell your doctor if unexpectedly you need to take any other medicines.
- Use the Axcel Orlistat Tablet according to the recommended dosage.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

Things you must not do

- Do not use your medicine more than the suggested frequency in a day.
- Do not over dosage the medicine during any single consumption.

Things to be careful of

- In order to ensure adequate nutrition, the use of multivitamin supplement could be considered.

Side effects

Like all medicines, Axcel Orlistat Tablet can cause side effects although not everybody gets them. You are advised to consult doctor/pharmacist for further information. The following common side effects have been reported:

- Oily spotting, flatus (fart) with discharge, sudden or frequent bowel movement, fatty / oily stool, oily evacuation, unable to control bowel movement.
- Abdominal pain / discomfort, flatulence (stomach bloating), liquid or soft stools, rectal pain / discomfort, tooth or gum disorder.

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- Upper respiratory infection, lower respiratory infection, influenza, headache, menstrual irregularity, anxiety, fatigue, and urinary tract infection.

Manufacturer and product registration holder

KOTRA PHARMA (M) SDN BHD
No. 1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers -> Reporting).

Date of revision

21/05/2015

Serial number

BPFK(R4/1)050515/00093

Storage and disposal of Axcel Orlistat Tablet

Storage

Keep Axcel Orlistat Tablet out of reach of children.

Store below 25°C. Keep container well closed and protect from light.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like

Axcel Orlistat-60 Tablet

Oval shape, engraved with 'KOTRa' on one side, film-coated light blue tablet.

Axcel Orlistat-120 Tablet

Oval shape, engraved with 'KOTRa' on one side, film-coated blue tablet.

Ingredients

Active Ingredient:

Orlistat

Inactive Ingredients:

Microcrystalline Cellulose, Sodium Starch Glycollate, Hydroxypropyl Cellulose, Magnesium Sterate, Purified Water and Opadry II Blue.

MAL Number

Axcel Orlistat-60 Tablet

MAL10120038A

Axcel Orlistat-120 Tablet

MAL10120039A