

CUVARLIX CAPSULE

Orlistat (120mg)

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What CUVARLIX Capsule is used for

It is used to treat obesity in conjunction with a low calorie intake diet. It is approved for obese individuals with a body mass index (BMI) of 30 or more kilograms / square meter in the presence of other risk factors, such as diabetes, high blood pressure, or high cholesterol.

How CUVARLIX Capsule works

CUVARLIX Capsule contains the active ingredient orlistat. It works in the digestive system to block the absorption of fat into the body from the food you eat.

Fats from the food you eat need to be broken down by enzymes called lipases before they can be absorbed into the body. Orlistat attaches to these enzymes in the digestive system and blocks them from breaking down about 30% of the fat you have eaten during your meal. The undigested fat cannot be absorbed and is then eliminated by your body.

Before you use CUVARLIX Capsule

-When you must not use it

Do not take CUVARLIX Capsule if you:-

- are allergic (hypersensitive) to CUVARLIX Capsule or to any of the other ingredients contained in CUVARLIX Capsule
- have chronic malabsorption syndrome (insufficient absorption of nutrients from alimentary tract)
- if you have cholestasis (liver disorder)

Pregnancy and lactation

Do not take CUVARLIX Capsule if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take CUVARLIX Capsule if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine if you are breast feeding.

-Before you start to use it

Inform your doctor or pharmacist before taking this medicine if you have:

- problems with your thyroid
- diabetes

If you are not sure if any of the above conditions apply to you, talk to your doctor or pharmacist before using CUVARLIX Capsule

-Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

CUVARLIX Capsule may modify the activity of

- Anticoagulant medicines (e.g. warfarin) -Your doctor may need to monitor your blood coagulation when you take CUVARLIX Capsule
- Ciclosporin – Using CUVARLIX Capsule with ciclosporin is not recommended. If you do use it, your doctor may need to monitor your ciclosporin blood levels more frequently than usual
- Amiodarone - You should ask your doctor for advice.
- Acarbose - CUVARLIX Capsule is not recommended for people taking acarbose (an anti-diabetic medication)
- Oral diabetic medication (e.g. (e.g. sulfonylureas, metformin) or insulin. Doctor might reduce the dose.

CUVARLIX Capsule reduces the absorption of fat soluble nutrients particularly beta-carotene and vitamin D.

You should therefore follow your doctor or pharmacist's advice in taking a well-balanced diet rich in fruit and vegetables and they may suggest you take a multivitamin supplement that contains fat-soluble vitamins. The supplement should be taken once a day at least 2 hours before or after taking orlistat, such as bedtime.

How to use CUVARLIX Capsule

-How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label of your medicine, ask your doctor or pharmacist for help.

Adults

The usual dose of CUVARLIX Capsule is one 120 mg capsule taken with each of the three main meals per day. It can be taken during a meal or up to one hour after a meal. The capsule should be swallowed with water.

CUVARLIX Capsule should be taken with a well-balanced, calorie controlled diet that is rich in fruit and vegetables and contains an average of 30 % of the calories from fat. Your daily intake of fat, carbohydrate and protein should be distributed over three meals. This means you will usually take one capsule at breakfast time, one capsule at lunch time and one capsule at dinner time.

To gain optimal benefit from the use of CUVARLIX Capsule, avoid the intake of food containing fat between meals, such as biscuits, chocolate and savoury snacks.

CUVARLIX Capsule only works in the presence of dietary fat. Therefore, if you miss a main meal or if you have a meal containing no fat, CUVARLIX Capsule need not be taken.

-When to use it

Use as directed by your doctor or pharmacist.

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-How long to use it

Continue taking CUVARLIX Capsule for as long as your doctor recommends.

-If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

-Things you must do

Take your medicine exactly as your doctor or pharmacist has told you.

When seeking other treatment, inform all the doctors, dentists and pharmacists that you are taking CUVARLIX Capsule.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give CUVARLIX Capsule to anyone else even if they have the same symptoms or condition as you.

-Things to be careful of

Weight loss may affect the dose of medicines taken for other conditions (e.g. diabetes). Be sure to discuss with your doctor or pharmacist about these medicines and any others you may be taking.

To gain the maximum benefit from CUVARLIX Capsule, you should follow

the nutrition program recommended to you by your doctor.

CUVARLIX Capsule can cause harmless changes in your bowel habits such as fatty or oily stools due to the elimination of undigested fat in your faeces. The possibility of this happening may increase if CUVARLIX Capsule is taken with a diet high in fat.

The use of an additional contraceptive method is recommended while you are using CUVARLIX Capsule to prevent possible failure of oral contraception that could occur in case of severe diarrhoea.

Side effects

Like all medicines, CUVARLIX Capsule can cause side effects, although not everybody gets them.

The majority of unwanted effects related to the use of CUVARLIX Capsule result from its action which is localized in your digestive system. These side effects occur at the beginning of treatment and are experienced particularly after meals containing high levels of fat. Normally, these symptoms disappear when you continue using CUVARLIX Capsule and keep to your recommended diet.

Very common side effects (affects more than 1 user in 10)

- headache,
- flu
- upper respiratory infection
- abdominal pain/discomfort
- increased defecation
- oily discharge
- oily or fatty stools
- liquid stools
- gas with little discharge
- oil evacuation
- low blood sugar levels

The effect of orlistat is seen as soon as 24 to 48 hours after dosing. Upon discontinuation of therapy, faecal fat content usually returns to pre-treatment levels, within 48 to 72 hours.

Common side effects (affects 1 to 10 users in 100)

- Rectal pain/discomfort
- soft stools
- fecal incontinence (uncontrolled)
- lower respiratory infection
- urinary tract infection
- tooth/gum disorder
- irregularity of menstrual cycle
- anxiety
- tiredness

Rare side effects (affects 1 to 10 users in 10 000)

- Allergic reactions - The main symptoms are itching, rash, swelling and severe difficulty in breathing.

Very rare side effects (affects less than 1 user in 10 000)

- Diverticulitis – Inflammation of diverticula (small pouches within the wall of the digestive tract), particularly in the colon.
- Increases in the levels of some liver enzymes may be found in blood tests.
- Hepatitis (inflammation of the liver). Symptoms can include yellowing of the skin and eyes, itching, dark coloured urine, stomach pain and liver tenderness (indicated by pain at the right side upper part of abdomen), sometimes with loss of appetite.
- Gallstones.

Oxalate nephropathy (buildup of calcium oxalate which may lead to kidney stones).

Stop taking CUVARLIX Capsule and see a doctor straight away if you notice any of the serious side effects listed above. You may need urgent medical treatment:

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 npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

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Storage and Disposal of CUVARLIX Capsule

- Storage

Keep out of reach and sight of children.
Store below 30°C. Protect from light.

Do not take CUVARLIX capsule after the expiry date stated on the label.

- 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

Turquoise/turquoise hard gelatin capsule with Pharmaniaga icon.

-Ingredients

- Active ingredient(s):

Each capsule contains Orlistat 120mg

- Inactive ingredient(s):

Microcrystalline Cellulose, Sodium Lauryl Sulphate, Povidone and Sodium Starch Glycolate

-MAL number(s):

MAL07050025AZ

Manufacturer

Pharmaniaga Manufacturing Berhad
(60016-D),
11A, Jalan P/1, Kawasan Perusahaan
Bangi, 43650 Bandar Baru Bangi,
Selangor Darul Ehsan, Malaysia.

Product Registration Holder

Pharmaniaga Manufacturing Berhad
(60016-D),
11A, Jalan P/1, Kawasan Perusahaan
Bangi, 43650 Bandar Baru Bangi,
Selangor Darul Ehsan, Malaysia.

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