
Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking Prolistat.

This leaflet answers some common questions about Prolistat. It does not contain all the available information.

Reading this leaflet does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking Prolistat against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine.

You may want to read it again.

What Prolistat is used for

Prolistat contains the active ingredient orlistat. It belongs to a group of medicines called lipase inhibitors. These medicines work by targeting the absorption of dietary fat in your body rather than suppressing your appetite.

Prolistat is used to treat people who are obese (BMI ≥ 30), or overweight (BMI ≥ 27) with other risk factors (e.g. high blood pressure, high cholesterol, and high blood lipid profile).

Your Body Mass Index (BMI) is calculated by dividing your weight (in kg) by your height (in metres) squared.

Dietary fats are large molecules that need to be broken down before they can be absorbed into the body. They are broken down by enzymes called lipases. Lipases play an important role in the digestion of dietary fat. When taken with a meal, orlistat interferes with the activity of these enzymes. This allows about 30% of the fat eaten in the meal to pass through the gut undigested. Therefore, your body cannot store these excess calories as fatty tissue or use them as a source of energy.

This helps you to reduce your weight by burning up fat that you are already carrying, maintain your lower weight and minimise any weight regain. Losing even small amounts of weight and keeping it off produces additional health benefits for you, especially when you are at risk for other diseases such as heart disease and diabetes.

Prolistat can also help to improve risk factors, such as high blood pressure, high cholesterol and high blood sugar. If these are not treated, they could lead to other diseases such as hypertension and diabetes.

Prolistat should be taken in conjunction with a well-balanced calorie-controlled diet and other appropriate measures such as exercise.

Ask your pharmacist or doctor if you have any questions or if you are not sure why Prolistat has been recommended for you.

Prolistat is not addictive.

Before you take Prolistat

Prolistat is not suitable for everyone.

When you must not take it

Do not take Prolistat if you have:

- chronic malabsorption syndrome (i.e. your body does not absorb essential nutrients as well as it should). This may occur with conditions such as tropical sprue and idiopathic steatorrhoea.
- certain pancreatic problems
- had recent major surgery to your stomach or intestines
- a blockage of your bile duct.

Do not take Prolistat if you are allergic to any medicine containing orlistat or any of the ingredients listed at the end of this leaflet.

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking Prolistat, talk to your pharmacist or doctor.

Before you start to take it

Tell your pharmacist or doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your pharmacist or doctor if you have or have had any medical conditions, especially the following:

- vitamin deficiencies
- kidney stones
- peptic (stomach) ulcer disease
- long-term treatment for mental or nerve disorders
- painful gall stones
- postsurgical adhesions
- eating disorders
- epilepsy or fits
- significant heart, kidney, liver, gastrointestinal or endocrine disorders
- taking oral contraceptives
- taking medicines for HIV
- have a thyroid disorder
- any other health problems.

Also tell your doctor if you are taking large doses of laxatives.

Do not take this medicine if you are pregnant or intend to become pregnant.

The safety of the use of this medicine in women who are pregnant or may become pregnant has not been established. Prolistat is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved.

Do not breast-feed if you are taking this medicine.

It is not known whether orlistat is excreted in human milk. Prolistat should not be taken during breast-feeding.

Do not give Prolistat to children or adolescents under 18 years.

There is not enough information to recommend the use of this medicine for children.

If you have not told your pharmacist or doctor about any of the above, tell them before you start taking Prolistat.

If you are taking oral contraceptives, commonly known as birth control pills, the use of an additional method of contraception is recommended. This is because you might experience severe diarrhoea whilst taking Prolistat which may decrease the absorption of oral contraceptive into your body. It is recommended that you use an additional method of contraception to prevent pregnancy.

Taking other medicines

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

Tell any healthcare professional who is prescribing a new medicine for you that you are taking Prolistat.

Some medicines and Prolistat may interfere with each other. These include:

- ciclosporin, a transplant rejection medicine
- warfarin or other anticoagulants (medicines that prevent blood clots)
- amiodarone, a medicine used to treat irregular heart beat
- acarbose and other medicines used to treat diabetes
- medicines used to treat epilepsy or fits
- other weight-loss medicines
- some vitamin supplements.
- medicines for HIV
- drugs to control hypothyroidism
- lithium and other medicines used for mental or sleep disorders.

The above medicines may be affected by Prolistat, or may affect how well it works. You may need different amounts, or take them at different times, or you may need to take different medicines. Because weight loss has many beneficial effects, it may also affect the dose of medicines taken for conditions such as high cholesterol or diabetes.

Be sure to discuss these and other medicines you may be taking with your pharmacist or doctor.

Losing weight may also mean you need adjustments to these medicines.

Your pharmacist and doctor have more information on medicines to be careful with or avoid while taking Prolistat.

How to take Prolistat

Read the label carefully and follow all directions given to you by your pharmacist and doctor.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your pharmacist or doctor for help.

How much to take

Adults 18 years and over

Take one 120 mg capsule three times a day.

Taking more than the recommended dose will not provide an additional benefit.

It is also recommended that you take a daily multivitamin supplement containing vitamins A, D, E and K.

Ask your pharmacist or doctor if you are unsure of the correct dose for you.

They will tell you exactly how much to take. This depends on your condition and whether or not you are taking any other medicines.

If you take the wrong dose, Prolistat may not work as well.

How to take it

Swallow the capsule whole with a full glass of water.

Prolistat should be taken with a well-balanced calorie controlled diet that is rich in fruit and vegetables and contains an average of 30% calories from fat. Your daily intake of fat, carbohydrate and protein should be distributed over 3 main meals. To gain the most benefit, avoid eating food containing fat between meals, such as biscuits, chocolate or savoury snacks.

Look out for fats in foods by reading all food labels. Your fat intake may also be reduced by removing all fat from meat, skin from chicken and using non-fat or low fat milk.

Be careful not to replace the fat in your diet with large quantities of other foods, such as sugar and alcohol.

For further dietary advice, refer to the NHMRC website at <http://www.nhmrc.gov.au>.

When to take it

Take 1 capsule with each of the 3 main meals per day.

This means that you will usually take one capsule at breakfast, lunch and dinner. It can be taken during the meal or up to 1 hour after the meal is consumed.

Prolistat only works in the presence of dietary fat in your body. Therefore, if you miss a main meal or if you know that the meal contains no fat, then Prolistat need not be taken.

How long to take it

Continue taking the medicine for as long as your pharmacist or doctor tells you to, for up to four years.

Take Prolistat every day for it to be effective.

Weight loss normally starts within 2 weeks and continues for 6 to 12 months on Prolistat treatment. Prolistat will then help you to maintain this new lower weight and help to prevent weight being regained.

The improvement in risk factors (such as reduction in high blood pressure, normalising blood sugar levels and lowering cholesterol levels) is usually observed within 1 month of starting therapy and is maintained during the course of treatment.

If you are unsure whether you should stop taking Prolistat, talk to your pharmacist or doctor.

If you forget to take it

If it is almost time for your next dose (i.e. close to your next meal), skip the dose you missed and take the next dose when you are meant to.

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

If you remember your missed dose *within 1 hour of your last meal*, take it and then take the next dose when you are meant to (i.e. after your next meal). Then go back to taking it as you would normally.

If you are not sure what to do, ask your pharmacist or doctor.

If you have trouble remembering to take your medicine, ask your pharmacist for hints.

While you are taking Prolistat

Things you must do

If you are about to be started on any new medicine, tell your pharmacist and doctor that you are taking Prolistat. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are being treated for epilepsy or fits, contact your pharmacist or doctor if you think that the frequency or severity of convulsions have changed while taking Prolistat.

Tell your pharmacist or doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your pharmacist or doctor may think that it was not effective and change your treatment unnecessarily.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may need you to have regular blood tests to monitor your blood sugar or blood cholesterol level.

To gain the most benefit from Prolistat you should follow the nutrition program recommended to you by your pharmacist or doctor. As with any weight-control program, over-consumption of fat and calories may counteract any weight loss effect.

See your pharmacist or doctor if you feel that Prolistat is not working.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

This medicine is only intended for the person it has been recommended for.

Do not take Prolistat to treat any other complaints unless your pharmacist or doctor tells you to.

Things to be careful of

Eat a well-balanced diet rich in fruit and vegetables.

People on a weight reduction diet may become deficient in some vitamins and minerals. To avoid this, follow your pharmacist's or doctor's advice on a well-balanced diet.

Take a multivitamin supplement containing vitamins A, D, E and K.

As this medicine works by preventing the absorption of some of the fat from the diet, it may affect absorption of some fat-soluble nutrients. Although most people taking Prolistat will still have normal vitamin levels, you should take a multivitamin supplement containing fat-soluble vitamins.

Take this supplement at least 2 hours before or after Prolistat, or at bedtime.

Distribute your daily intake of fat over 3 main meals.

This medicine can cause harmless changes in your bowel habits, such as fatty or oily stools. This is due to the removal of undigested fat in your faeces. The possibility of this happening will increase if Prolistat is taken with a diet high in fat. In addition, your daily intake of fat should be distributed over 3 main meals. If Prolistat is taken with any one meal very high in fat, the possibility of unwanted effects on the digestive system will increase.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Prolistat affects you.

Prolistat may cause dizziness in some people.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Alcohol is not expected to interact with Prolistat.

Things that may help your condition

Increase your level of exercise as it will help with weight loss.

Because increased exercise will help weight loss, it is advisable to follow a regular exercise program (e.g. walking, swimming).

See your doctor before starting any exercise program.

In case of overdose

If you take too much

Immediately telephone your pharmacist or doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Prolistat.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Prolistat.

Like all medicines, Prolistat may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your pharmacist or doctor to answer any questions you may have.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- increased flatulence (wind) with or without discharge
- urgent need to have a bowel movement
- frequent bowel movements
- oily, fatty, soft or liquid stools
- abdominal pain
- oily discharge from anus
- rectal pain or discomfort.
- gum disease (swollen, painful bleeding gums)

Tell your pharmacist or doctor if you have type II diabetes and you notice any of the following and they worry you:

- bloating

- hypoglycaemia (symptoms include: sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, fast pounding heart).

These are more common side effects. They normally occur at the beginning of treatment and usually go away if you continue treatment and keep to your recommended diet. These symptoms are generally mild and are usually experienced after meals containing high levels of fat.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- nausea (feeling sick)
- dyspepsia (indigestion)
- headache
- anxiety
- menstrual irregularities
- asthenia (unusual tiredness or weakness)
- signs of respiratory infection such as coughing, runny nose, shortness of breath, and/or fever
- signs of urinary tract infection such as going to the toilet more frequently, burning sensation when passing urine and/or lower back pain
- blistering of the skin
- back pain.
- severe and continuous rectal bleeding
- hypothyroidism (tiredness, lethargy, muscle weakness, cramps, feeling the cold, a slow heart rate, dry and flaky skin, hair loss, a deep and husky voice, weight gain).

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- serious allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing)
- symptoms of liver disease (hepatitis) such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine
- unexplained bleeding, bruising or blood in your urine.
- symptoms of inflammation of the pancreas such as severe upper stomach pain, often with nausea and vomiting.

These are very serious side effects; you may need urgent medical attention or hospitalisation.

Tell your pharmacist or doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking Prolistat

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

Keep Prolistat in a cool dry place where the temperature stays below 25°C. Store

in original container in order to protect from light and moisture.

Do not store it or any other medicine in the bathroom, near a sink, or on a window sill. Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it and any other medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not keep Prolistat past its expiry date.

Disposal

Return any unused medicine and any medicine past its expiry date (as shown on the labelling) to your pharmacy.

Product description

What it looks like

Prolistat is available in blister packs of 42 or 84 capsules. The capsules are blue in colour and contain a white powder or slightly compacted agglomerates.

Ingredients

Active ingredient:

- orlistat 120 mg

Inactive ingredients:

- microcrystalline cellulose
- sodium starch glycolate type A
- hydrophobic colloidal silica anhydrous
- sodium lauryl sulfate
- gelatin
- indigo carmine
- titanium dioxide.

Prolistat does NOT contain lactose, sucrose, tartrazine or any other azo dyes.

Sponsor details

Boucher & Muir Pty Ltd
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AUST R 268252

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