

PRO-BANTHINE™ TABLET

propantheline bromide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PRO-BANTHINE tablets. It does not contain all the available information about this medicine. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PRO-BANTHINE against the benefits he or she expects it will have.

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

Keep this leaflet with the medicine.

You may need to read it again.

What is PRO-BANTHINE used for

The name of your medicine is PRO-BANTHINE.

The active ingredient is called *propantheline bromide*.

Propantheline bromide belongs to a group of medicines called the anticholinergics.

Anticholinergics are used to reduce both gastric acid and other secretions in the stomach, and to reduce cramps or spasms in the muscles of your stomach, intestine and urinary tract.

PRO-BANTHINE works by stopping some of the actions of a naturally occurring substance called acetylcholine which then reduces:

- the amount of acid produced by your stomach
- cramps or spasms in the muscles of your stomach, intestine and urinary tract
- the amount of sweat produced by your body

PRO-BANTHINE is used to treat a number of different conditions:

It reduces:

- ulcers in the stomach (gastric ulcers) and in the first part of the intestine (duodenal ulcers) with the assistance of other medicines
- urinary problems caused by nerves or muscles that control the bladder
- excessive sweating

Your doctor may have prescribed this medicine for another condition.

Ask your doctor if you have any questions about why PRO-BANTHINE has been prescribed for you.

PRO-BANTHINE tablets are only available with a doctor's prescription.

This medicine is not recommended for use in children.

Before you take it

When you must not take it

Do not take PRO-BANTHINE if you are allergic to:

- propantheline bromide or any other anticholinergic agent
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction to PRO-BANTHINE may include red, itchy skin rashes, difficulty in breathing, swelling of the face or throat or faintness.

Do not take PRO-BANTHINE if you have any of the following medical conditions:

- Glaucoma, high pressure in the eye
- heart problems
- Thyrotoxicosis, a condition of excessive thyroid hormones
- obstructive gastrointestinal problems
- prostate problems
- intestinal problems, including colitis
- Myasthenia gravis
- obstructive urinary tract problems
- hiatus hernia (belching and heartburn)
- acute bleeding

Do not use this medicine after the expiry date (EXP.) printed on the pack.

If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must tell your doctor if:

1. **you are allergic to any other medicines or any foods, dyes or preservatives**
2. **you are pregnant or intend to become pregnant**

PRO-BANTHINE is rated in Australia as a Category B2 drug for the use in pregnancy. Your doctor will discuss the risks and benefits of taking PRO-BANTHINE during pregnancy.

3. **you are breast-feeding or intend to breastfeed**

Special care is recommended if you are breast-feeding, as no studies have been conducted in breast-feeding mothers. Your doctor will discuss the risks and benefits of taking PRO-BANTHINE during breast-feeding.

Elderly patients are more likely to have less effective kidney or liver function due to age. This may increase the risk of side effects.

You should discuss how much PRO-BANTHINE to take with your doctor or pharmacist.

4. **You have any other medical conditions/ health problems, including:**

- stomach and intestinal problems, including colon inflammation, small bowel not working properly
- heart diseases
- lung problems
- fever or exposure to high environmental temperatures
- bleeding disorders
- an overactive thyroid gland
- high blood pressure
- liver and/or kidney disease
- problems with the nervous system
- down's syndrome

- hereditary intolerances such as galactose, lactose, fructose, glucose, sucrose-isomaltose.

If you have not told your doctor about any of the above, tell them before you start to take any PRO-BANTHINE.

Taking other medicines

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

SOME medicines may interact with PRO-BANTHINE.

These include:

- antacids and anti-diarrhoeals
- *digoxin*, a medicine used to treat heart failure
- medicine used for stomach cramps or spasms
- painkillers e.g. *pethidine*, *nefopam*, and *paracetamol*
- anti-parkinson drugs e.g. *levodopa*
- anti-arrhythmics, medicines used to treat irregular heart beats e.g. *disopyramide*, *procainamide* or *quinidine*
- antihistamines, medicines used to prevent or relieve symptoms of allergy
- antidepressants, medicines used to treat depression
- *metoclopramide* and *domperidone*, medicines used to treat nausea
- *ketoconazole*, medicine used to treat fungal infections
- potassium chloride
- *cisapride*, medicine that stimulates stomach muscle contraction
- medicines used to treat the condition myasthenia gravis
- urinary alkalinisers
- medicines used to treat certain mental and emotional conditions
- corticosteroids, e.g. *prednisolone*, *cortisone*
- other anticholinergics
- *memantine*, medicine used to treat Alzheimer's
- nitrates
- other anti-infectives

The above medicines may either reduce the effectiveness of PRO-BANTHINE, reduce its own effectiveness and/or react with PRO-BANTHINE resulting in untoward or sometimes dangerous side effects.

This list is not exhaustive.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking PRO-BANTHINE.

Before you start to take any other medicine, tell your doctor or pharmacist that you are taking PRO-BANTHINE.

How to take it

Follow your doctor's instructions carefully, as they may differ from the information contained in this leaflet.

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

How much to take

The recommended doses of PRO-BANTHINE are:

For treatment of peptic ulcers

Adults: 1 tablet three times daily and 2 tablets at bedtime.

For treatment of other conditions

Adults: 1 to 2 tablets four times daily.

The safety and efficacy of PRO-BANTHINE in children has not been established.

Different people respond differently to PRO-BANTHINE, so your doctor may tell you to take a different dose.

Do not change your dose of PRO-BANTHINE unless your doctor tells you to do so.

Do NOT take more than 8 tablets in one day.

How to take it

PRO-BANTHINE tablets should be swallowed with a glass of water.

When to take it

Take your PRO-BANTHINE tablets 30 minutes before a meal.

How long to take it

Continue taking PRO-BANTHINE as long as your doctor recommends it.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take your dose as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

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

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

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

If you take too much (Overdose):

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much PRO-BANTHINE. Do this even if there are no signs of discomfort or poisoning. Also report any other medicine or alcohol which has been taken. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you take too much PRO-BANTHINE you may have the following symptoms: Increased severity of the side effects listed; changes in behaviour such as restlessness and excitement; flushing of the skin; a fall in blood pressure; breathing difficulties; and paralysis.

While you are using it

Things you must do

Immediately stop taking PRO-BANTHINE if a skin rash or other allergic reaction occurs.

Use PRO-BANTHINE exactly as directed or as your doctor has prescribed.

Tell any other doctors, dentists or pharmacists who are treating you that you are taking PRO-BANTHINE.

Tell your doctor if you become pregnant while taking PRO-BANTHINE.

Tell your doctor if you feel PRO-BANTHINE is not helping your condition.

Visit your doctor regularly.

Your doctor needs to check your progress and see whether you need to stop taking PRO-BANTHINE.

Always discuss with your doctor any problems or difficulties during or after taking PRO-BANTHINE.

Things you must not do

Do not take any other medicines while you are taking PRO-BANTHINE without first telling your doctor.

Do not drive, operate machinery, or participate in dangerous activities where alertness is required, until you know how PRO-BANTHINE affects you.

PRO-BANTHINE may cause drowsiness or dizziness in some people and therefore may affect alertness. PRO-BANTHINE can also affect your eyesight by blurring your vision.

Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

Things you must be careful of

Be careful when exercising or when the weather is hot.

Make sure you keep cool in hot weather and keep warm in cool weather.

PRO-BANTHINE may affect the way your body reacts to temperature changes. It may prevent sweating, even during heatwaves. Hot baths or saunas may make you feel dizzy or faint while you are taking this medicine.

Side effects

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

You may not experience any of them.

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

PRO-BANTHINE helps most people with the medical conditions listed in the beginning of this leaflet, but it may have unwanted side effects in some people.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist any questions you may have.

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

- thirstiness
- dry mouth
- dry skin
- difficulty in swallowing and talking
- nervousness
- drowsiness
- dizziness
- weakness
- confusion
- headache
- blurred vision

- nausea
- vomiting
- bloatedness
- constipation
- flushing
- inability to sleep
- decreased sweating
- loss of sense of taste
- impotence
- reduction in the amount of breast milk

These side effects are usually mild.

Tell your doctor or pharmacist immediately if you notice any of the following:

- skin rash
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- unable to pass urine
- difficulty passing urine
- fever
- fast, pounding or irregular heartbeats

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor or pharmacist immediately or go to casualty at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue, or other parts of the body, shortness of breath, wheezing or trouble breathing

This is a very serious side effect. You may need urgent medical attention or hospitalisation. This side effect is very rare. Some people may get other side effects with PRO-BANTHINE.

Check with your doctor as soon as possible if you have any problems while taking PRO-BANTHINE, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

After using it

Storage

Keep your tablets in the bottle they were provided in until it is time to take them.

Keep it where children cannot reach it.

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

Keep PRO-BANTHINE in a cool dry place where the temperature stays below 30°C and protect from light.

Do not store it, or any other medicines in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Do not take PRO-BANTHINE if the tablets do not look quite right.

Disposal

If your doctor tells you to stop taking this medication OR it has passed its expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

PRO-BANTHINE 15 mg tablets are pale orange, film coated tablets in bottles of 100.

Ingredients

Each PRO-BANTHINE tablet contains 15 mg of propantheline bromide as the active ingredient.

The other ingredients in each tablet are:

- lactose
- starch-maize
- magnesium stearate
- talc-purified
- Opadry II complete film coating system
85G63218 Orange

PRO-BANTHINE tablets contain soya bean and sugars as lactose, but do NOT contain any gluten.

Sponsor or Supplier

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113
Australia

The Australian Registration Number for PRO-BANTHINE 15 mg tablets is AUST R 207283.

This leaflet revised in June 2022.