

PRO-BANTHINE TABLET

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using PRO-BANTHINE?

PRO-BANTHINE contains the active ingredient propantheline bromide. PRO-BANTHINE is used to treat number of conditions like gastric ulcers, duodenal ulcers, urinary problems caused by nerves or muscles that control bladder, excessive sweating, For more information, see Section [1. Why am I using PRO-BANTHINE?](#) in the full CMI.

2. What should I know before I use PRO-BANTHINE?

Do not use it if you have ever had an allergic reaction to PRO-BANTHINE or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use PRO-BANTHINE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PRO-BANTHINE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use PRO-BANTHINE?

- PRO-BANTHINE tablet should be swallowed with a glass of water.
- Take your PRO-BANTHINE tablets 30 minutes before a meal.

More instructions can be found in Section [4. How do I use PRO-BANTHINE?](#) in the full CMI.

5. What should I know while using PRO-BANTHINE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using PRO-BANTHINE.• Use PRO-BANTHINE exactly as directed or as your doctor has prescribed.
Things you should not do	<ul style="list-style-type: none">• Do not take any other medicines while you are taking PRO-BANTHINE without first telling your doctor.• Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.
Driving or using machines	<ul style="list-style-type: none">• 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.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• Alcohol may interfere with PRO-BANTHINE
Looking after your medicine	<ul style="list-style-type: none">• 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.

For more information, see Section [5. What should I know while using PRO-BANTHINE?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects like thirstiness, dry mouth, dry skin, difficulty n 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 tell your doctor immediately.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PRO-BANTHINE TABLET

Active ingredient(s): propantheline bromide

Consumer Medicine Information (CMI)

This leaflet provides important information about using PRO-BANTHINE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PRO-Banthine.**

Where to find information in this leaflet:

- [1. Why am I using PRO-BANTHINE?](#)
- [2. What should I know before I use PRO-BANTHINE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PRO-BANTHINE?](#)
- [5. What should I know while using PRO-BANTHINE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using PRO-BANTHINE?

PRO-BANTHINE contains the active ingredient propantheline bromide. PRO-BANTHINE belongs to group of medicines called the anti-cholinergic.

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 is used to treat a number of different conditions:

It reduces:

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

2. What should I know before I use PRO-BANTHINE?

Warnings

Do not use PRO-BANTHINE if:

- you are allergic to propantheline bromide or any other anticholinergic agent, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

- Some of the symptoms of an allergic reaction to PRO-BANTHINE may include red, itchy, skin rashes.

Check with your doctor if you:

- have any other medical conditions:
- Glaucoma, high pressure in the eye
- 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 heart burn)
- Acute bleeding
- take any medicine for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Special care is recommended if you if you are breastfeeding, 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.

Before you start to take it

- You are allergic to any other medicines or any foods, dyes or preservatives.
- 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 nervous system
- Downs syndrome
- Hereditary intolerances such as galactose, lactose, fructose, glucose, sucrase-isomaltase

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

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

3. What if I am taking other medicines?

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

Some medicines may interfere with PRO-BANTHINE and affect how it works. These include:

- Antacids and anti-diarrhoeals
- Digoxin, a medicine used to treat heart failures
- 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
- anti-depressants, 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
- medicine 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PRO-BANTHINE.

4. How do I use PRO-BANTHINE?

How much to take / use

- Follow your doctor's instructions carefully, as they may differ from the information contained in this leaflet.
- Follow the instructions provided and use PRO-BANTHINE until your doctor tells you to stop.
- If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

When to take / use PRO-BANTHINE

- PRO-BANTHINE tablets should be consumed 30 minutes before a meal.

If you forget to use PRO-BANTHINE

PRO-BANTHINE should be used regularly at the same time each day. If you miss your dose at the usual time, take your dose as soon as you remember, and then go back to taking it as you would normally.

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

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

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

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

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

If you use too much PRO-BANTHINE

If you think that you have used too much PRO-BANTHINE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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 behavior such as restlessness and excitement; flushing of the skin; a fall in blood pressure; breathing difficulties; and paralysis.

5. What should I know while using PRO-BANTHINE?

Things you should do

Call your doctor straight away if you:

- Develop a skin rash or other allergic reaction occurs.
- If you feel PRO-BANTHINE is not helping your condition.

Remind any doctor, dentist, or pharmacist you visit that you are using PRO-BANTHINE.

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 should not do

- Do not take any other medicines while you are taking PRO-BANTHINE without first telling your doctor.
- Do not give this medicine to anyone else, even if his or her symptoms seem like 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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. [or insert relevant information, as appropriate].

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may interfere with PRO-BANTHINE.

Looking after your medicine

- Keep your tablets in the bottle they were provided in until it is time to take them.
- Keep PRO-BANTHINE in a cool dry place where the temperature stays below 30°C and protect from light.
- Heat and dampness can destroy some medicines.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

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

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

When to discard your medicine (as relevant)

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 leftover medication.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Thirstiness • Dry mouth • Dry skin • Difficulty in swallowing and talking • Nervousness • Drowsiness • Dizziness • Weakness • Confusion • Headache • Blurred vision • Nausea • Vomiting • Bloating • Constipation • Flushing • Inability to sleep • Decreased sweating • Loss of sense of taste • Impotence • Reduction in the amount of breast milk 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>[Insert appropriate action]</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Skin rash • Pinkish, itchy swelling on the skin, also called hives or nettles rash • Unable to pass urine • Difficulty passing urine • Fever • Fast, pounding or irregular heart beats 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Very Serious side effects

Very Serious side effects	What to do
<ul style="list-style-type: none"> • 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. • 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What PRO-BANTHINE contains

Active ingredient (main ingredient)	Propantheline bromide
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Lactose • Starch maize • Magnesium stearate • Talc-purified • Opadry II complete film coating system 85G63218 Orange
Potential allergens	Soya bean and sugars as lactose, but does NOT contain any gluten

Do not take this medicine if you are allergic to any of these ingredients.

What PRO-BANTHINE looks like

PRO-BANTHINE 15mg tablets are pale orange film coated tablets in bottles of 100. (Aust R 207283).

Who distributes PRO-BANTHINE

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia

This leaflet was prepared in November 2023.