

PACKAGE LEAFLET: INFORMATION FOR THE USER

PRO-BANTHINE® 15mg TABLETS

proprantheline bromide

Please read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you suffer from any of the side effects that get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT PRO-BANTHINE TABLETS ARE AND WHAT THEY ARE USED FOR

Pro-Banthine tablets contain the active ingredient proprantheline bromide which belongs to a group of drugs known as "antispasmodics". They work by relaxing the muscles of the intestines.

Pro-Banthine tablets are used to treat disorders in the gastrointestinal tract which involve muscle spasm. They are also for use by adults who have problems holding their urine, which results in wetting (enuresis), and excessive sweating (hyperhidrosis).

2. BEFORE YOU TAKE PRO-BANTHINE TABLETS

Do not take Pro-Banthine Tablets if you have:

- an **allergy** to proprantheline bromide or any of the other ingredients of Pro-Banthine (see Section 6, and also end of Section 2)
- an **obstruction** in your **gut** (gastrointestinal tract), or it is inflamed or does not function normally. These may show themselves as abdominal pain, bloating, reflux or fever
- a **hiatus hernia** (a condition in which a portion of the stomach protrudes upward into the chest, through an opening in the diaphragm)
- **pyloric stenosis** (a narrowing of the outlet from your stomach which delays food passing out of your stomach and may lead to vomiting)
- **severe ulcerative colitis** (ulcers and inflammation in the large bowel), as Pro-Banthine tablets may worsen the condition
- any **obstruction** in your urinary tract
- a **muscle weakening disease** such as myasthenia gravis or weakness of the intestinal muscles
- **heart problems** following severe bleeding
- an enlarged **prostate gland**
- an **eye disease** called closed angle glaucoma.

These tablets are not recommended for children.

Take special care with Pro-Banthine tablets

You should consult your doctor **before** taking Pro-Banthine if any of the following conditions applies to you:

- pregnancy, likely to become pregnant or are breast-feeding
- elderly
- diarrhoea, especially if you have a colostomy (opening of the colon by surgery) or ileostomy (opening of the small intestine by surgery)

- severe heart disease, especially if an increase in heart rate is undesirable, or an irregular heart beat, heart failure, reduced heart function or any other heart problem (coronary heart disease, congestive heart failure, cardiac arrhythmias)
- gastrointestinal reflux
- a fever
- ulcerative colitis (ulcers and inflammation in the large bowel) as taking Pro-Banthine tablets may result in life-threatening complications of other intestinal conditions
- autonomic neuropathy (a disease of the nervous system affecting the bladder muscles, the heart, the digestive tract, and the genital organs)
- liver or kidney problems
- an overactive thyroid gland
- high blood pressure
- Down's syndrome.

Pro-Banthine tablets may also induce fever and heat stroke in patients in hot weather due to decreased sweating.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines, because Pro-Banthine may interact with them:

- **nefopam** (a pain killer): the risk of side effects may increase if you take Pro-Banthine tablets
- **paracetamol**: its absorption may be reduced by Pro-Banthine tablets
- medicines to reduce **high blood pressure**: Pro-Banthine tablets may increase the risk of side effects
- **anti-diabetic medicines**: your insulin requirement may be reduced if you take Pro-Banthine tablets
- **antidepressants**: Pro-Banthine tablets may increase the risk of side effects
- **disopyramide** (to treat irregular heartbeat): Pro-Banthine tablets may increase the risk of side effects
- **ketoconazole** (to treat fungal infections): Pro-Banthine tablets may reduce its absorption
- **nitrofurantoin** (to treat infections): Pro-Banthine tablets may enhance its absorption
- **antihistamines**: Pro-Banthine tablets may increase the risk of side effects
- **antimuscarinic drugs** such as belladonna alkaloids (to affect the nervous system): Pro-Banthine tablets may increase the risk of side effects
- **haloperidol** (to treat psychosis): Pro-Banthine tablets may reduce its effects
- **clozapine or phenothiazines** (to treat psychosis): Pro-Banthine tablets may increase the risk of side effects
- **digoxin** (to treat heart failure): taking Pro-Banthine tablets with slow-dissolving digoxin tablets may cause increased digoxin levels in your blood
- **domperidone** (to treat nausea and vomiting): Pro-Banthine tablets may reduce its effects on gastrointestinal activity
- **amantadine** (to treat Parkinson's disease and some viral infections): Pro-Banthine tablets may increase the risk of side effects
- **levodopa** (to treat Parkinson's disease): Pro-Banthine tablets may reduce its absorption
- **memantine** (to treat dementia in Alzheimer's disease): the effects of Pro-Banthine tablets may be enhanced by memantine
- **metoclopramide** (to treat nausea, vomiting and migraine): Pro-Banthine tablets may reduce its effects on gastrointestinal activity
- **nitrates** (to treat angina): Pro-Banthine tablets may reduce the effects of sublingual nitrate tablets (failure to dissolve under the tongue owing to dry mouth)

- **parasympathomimetics** (drugs that are used to affect the nervous system e.g. stimulating digestive secretions; slowing the heart; constricting the pupils; dilating blood vessels): Pro-Banthine tablets may reduce the effects of these drugs.

If you are not sure which medicines you are already taking, please ask your doctor or pharmacist.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant or think you may be pregnant or planning to become pregnant. You should not take this medicine when pregnant unless told to by your doctor.

Do not breast-feed if you are taking Pro-Banthine tablets unless told to by your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or use machinery as Pro-Banthine tablets may make you feel drowsy or cause blurred vision.

Important information about some of the ingredients of Pro-Banthine Tablets

Lactose and **sucrose** are ingredients present in Pro-Banthine tablets – if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

3. HOW TO TAKE PRO-BANTHINE TABLETS

Always take Pro-Banthine tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Tablets should be taken at least one hour before meals as food affects their action. Swallow the tablets whole with some water.

Adults:

The usual starting dose is one tablet before each meal and two tablets at bedtime. Your doctor will then adjust the dose according to your response to the tablets. This may be increased to a maximum of eight tablets a day.

Elderly:

The dosage is the same as stated for adults, but the elderly should take special care when taking Pro-Banthine tablets because they are more susceptible to the side effects.

Children:

Pro-Banthine tablets are not recommended for use in children.

If you forget to take Pro-Banthine Tablets

If you forget to take your tablets, take your next dose as soon as you remember unless it is time for your next dose. Do not take two doses at the same time. If in doubt about what you should do, please contact your doctor or pharmacist.

If you take more Pro-Banthine Tablets than you should

If you accidentally take more tablets than you should, or you suspect that a child has swallowed the tablets, contact your doctor straight away or go to your nearest hospital casualty department immediately. Take this leaflet and the pack of tablets along with you, if you can. Symptoms of excessive overdosage are restlessness, hallucinations, delirium, convulsion, circulatory failure, respiratory depression, and coma.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pro-Banthine tablets can cause side effects, although not everybody gets them.

Stop taking Pro-Banthine tablets and seek immediate medical attention if you experience any of the following:

- Eye pain, severe difficulty focusing your eyes or being very sensitive to light
- Severe difficulty urinating and emptying the bladder.

Tell your doctor if you experience any of the following:

- increase or decrease in your heart rate; palpitations (unpleasant or unusual sensation of your heart beating) or irregular heartbeat
- difficulty focusing your eyes and being sensitive to light. Pro-Banthine tablets may also cause an increase in the pressure of fluid in the eye, you may experience this as eye discomfort or pain
- difficulty urinating and emptying the bladder
- constipation
- nausea and vomiting
- dry mouth, feeling thirsty and finding it difficult to swallow
- dry skin, feeling hot with reddening of the face and neck but with very little sweating
- dryness of the airways (this may make it difficult to cough up phlegm)
- confusion in the elderly
- dizziness.

If you are elderly, you may be particularly sensitive to the side effects of Pro-Banthine tablets. Tell your doctor immediately if you experience any of the side effects listed above.

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE PRO-BANTHINE TABLETS

Keep out of the reach and sight of children.

Keep the tablets in the original pack and store below 25°C.

Do not use Pro-Banthine tablets after the expiry date which is stated on the carton after 'Expiry:' and on blister after 'Exp:'. The expiry date refers to the last day of that month.

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.

6. FURTHER INFORMATION

What Pro-Banthine Tablets contain

The active substance in each tablet is propantheline bromide 15mg.

The other ingredients in the tablet are: lactose, corn starch, talc, light liquid paraffin and magnesium stearate.

The sugar coating contains: sucrose, calcium carbonate, saccharin sodium, titanium dioxide (E171), magnesium carbonate, castor oil, talc, red oxide (E172), ochre no.1624 (E172), carnauba wax and water.

(see also end of Section 2 "Important information about some of the other ingredients of Pro-Banthine Tablets" for lactose and sucrose.

What Pro-Banthine Tablets look like and contents of the pack
Pro-Banthine Tablets are unmarked, pink, sugar-coated tablets.

The tablets are supplied in blister packs containing 100 or 112 tablets or in bottles containing 1000 or 5000 tablets.

Marketing Authorisation Holder

Archimedes Pharma UK Limited
250 South Oak Way, Green Park
Reading RG2 6UG
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Manufacturer

Haupt Pharma Wülfing GmbH
Bethelner Landstrasse 18
31028 Gronau
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