PACKAGE LEAFLET: INFORMATION FOR THE USER

PRO-BANTHINE® 15mg TABLETS

Propantheline bromide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 signs of illness are the same as yours.
- If you get any side effects talk to you doctor or pharmacist This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT PRO-BANTHINE IS AND WHAT IT IS USED FOR

Pro-Banthine tablets contain the active ingredient propantheline 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. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PRO-BANTHINE TABLETS

Do not take Pro-Banthine tablets if you have:

- an **allergy** to propantheline 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 partial or complete **blockage** of the **bowel** that leads to constipation or bloating of the stomach (paralytic ileus)
- **toxic megacolon** (a very dilated colon accompanied by bloating and sometimes fever, abdominal pain or shock)
- 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.

Warning and Precautions
Talk to your doctor or pharmacist **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

Pro-Banthine should be used with caution in elderly patients and patients with Down's syndrome.

These tablets may induce fever and heat stroke in patients in hot weather due to decreased sweating.

Children
These tablets are not recommended for children.

Other Medicines and Pro-Banthine tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

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, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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.

Pro-Banthine tablets contain lactose and sucrose
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. 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.

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 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, paralysis of voluntary muscles and coma.

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 a double dose to make up for a forgotten dose. If in doubt about what you should do, please contact your doctor or pharmacist.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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
- constipation
- nausea (feeling sick) 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, heat stroke
- 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.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme.
Website: www.mhra.gov.uk/yellowcard

Ireland:
HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2
Tel: +353 1 6764971, Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

5. HOW TO STORE PRO-BANTHINE TABLETS

Keep out of the sight and reach of children.
Keep the tablets in the original pack to protect from light and store below 25ºC.

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 monohydrate, corn (maize) 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 iron oxide (E172), ochre no.1624 (E172), carnauba wax and water.
(see also end of Section 2 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. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Archimedes Pharma UK Limited
Galabank Busines Park
Galashiels
TD1 1QH
United Kingdom

Manufacturer
Haupt Pharma Wülfing GmbH
Bethelner Landstrasse 18
31028 Gronau
Germany
PL 12406/0026
PA 0757/009/001

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