Product:	**Propantheline 15 mg Tablets**
MA Holder:	**Chelonia**
PL No.:	**33414/0094**
Pack Size:	**All**
Livery:	**Chelonia**
Manufacturer:	**-**
Market:	**UK**
Component:	**Leaflet**

Printing Colours:
Black

Non-Printing Colours:
Profile

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Chelonia HEALTHCARE

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Prompt list for artwork checks

Are the dimensions correct?
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Pharmacode

PACKAGE LEAFLET: INFORMATION FOR THE USER

PROPANTHELINE 15 MG 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 only. 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 your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET

1. **What Propantheline is and what it is used for**
2. **What you need to know before you take Propantheline Tablets**
3. **How to take Propantheline Tablets**
4. **Possible side effects**
5. **How to store Propantheline Tablets**
6. **Contents of the pack and other information**

1. WHAT PROPANTHELINE IS AND WHAT IT IS USED FOR

The name of this medicine is Propantheline tablets 15 mg. It contains an active substance called Propantheline Bromide BP. The tablets belong to a group of medicines known as "anti-spasmodics" which act by relaxing the muscles of the intestines.

This medicine is used for the treatment of disorders in the gastrointestinal tract which involve muscle spasm. They are also used for adults who have problems holding their urine, which results in wetting (enuresis), and for excessive sweating (hyperhidrosis).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PROPANTHELINE TABLETS

Do not take Propantheline tablets if you have:
- an allergic to propantheline bromide or any of the other ingredients of this medicine (listed in section 6).
- 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 propantheline tablets may worsen the condition
- any obstruction in your urinary tract
- myasthenia gravis (weakening of the muscles)
- heart problems following severe bleeding
- an enlarged prostate gland
- an eye disease called closed angle glaucoma.

Warnings and precautions
Talk to your doctor or pharmacist before taking Propantheline Tablets if you:
- are pregnant, planning a pregnancy or are breast-feeding
- are elderly
- have diarrhoea, especially if you have colostomy (opening of the colon by surgery) or ileostomy (opening of the small intestine by surgery)
- have severe heart disease, especially if an increase in heart rate is undesirable, or an irregular heartbeat, 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 propantheline tablets may result in life threating 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

Propantheline 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.

Other medicines and propantheline 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, as they may affect how Propantheline works;
- nefopam (a pain killer): the risk of side effects may increase if you take Propantheline tablets
- paracetamol: its absorption may be reduced by Propantheline tablets
- antidepressants: Propantheline tablets may increase the risk of side effects
- disopyramide (to treat irregular heartbeat): Propantheline tablets may increase the risk of side effects
- ketoconazole (to treat fungal infections): Propantheline tablets may reduce its absorption
- nitrofurantoin (to treat infections): Propantheline tablets may enhance its absorption
- antihistamines: Propantheline tablets may increase the risk of side effects
- antimuscarinic drugs such as belladonna alkaloids (to affect the nervous system): Propantheline tablets may increase the risk of side effects
- haloperidol (to treat psychosis): Propantheline tablets may reduce its effects
- clozapine or phenothiazines (to treat psychosis): Propantheline tablets may increase the risk of side effects
- digoxin (to treat heart failure): taking Propantheline tablets with slow-dissolving digoxin tablets may cause increased digoxin levels in your blood
- domperidone (to treat nausea and vomiting): Propantheline tablets may reduce its effects on gastrointestinal activity.
- amantadine (to treat Parkinson's disease and some viral infections): Propantheline tablets may increase the risk of side effects
- levodopa (to treat Parkinson's disease): Propantheline tablets may reduce its absorption
- memantine (to treat dementia in Alzheimer's disease): the effects of Propantheline tablets may be enhanced by memantine
- metoclopramide (to treat nausea, vomiting and migraine): Propantheline tablets may reduce its effects on gastrointestinal activity

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- nitrates (to treat angina): Propantheline 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 eg; stimulating digestive secretions, slowing the heart, constricting the pupils, dilating the blood vessels): Propantheline tablets may reduce the effects of these drugs.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Propantheline Bromide tablets 15 mg should not be used in pregnancy unless the doctor considers it essential.
It is not known whether Propantheline Bromide passes into human breast milk, and in view of this Propantheline Bromide tablets 15 mg should not be used during breast-feeding unless considered absolutely essential.

Driving and using machines.
Propantheline Bromide tablets 15 mg may produce drowsiness or blurring of vision and therefore you should not drive or operate machinery if affected in this way.

Propantheline tablets contain lactose.
Propantheline tablets contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

Propantheline tablets contain sunset yellow FCF (E110).
Propantheline tablets contains sunset yellow FCF (E110), which may cause allergic reactions.

3. HOW TO TAKE PROPANTHELINE TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is

Adults:
The initial starting dose is 1 tablet before each meal and 2 tablets at bedtime. Subsequently the dosage should be adjusted according to the individual response to this medicine.

The maximum up to 8 tablets daily in divided doses may be required.

Elderly:
The dose is the same as for adults. However, the elderly should take special care when taking propantheline tablets because they are more likely to experience side-effects.

Children:
These tablets are not recommended for use in children.
This medicine is to be taken by mouth at least one hour before meals as food affects their action.

If you take more Propantheline tablets than you should
If you think you have taken too many of your tablets, call your doctor straight away or go the nearest hospital casualty department. Always keep any remaining tablets in the container in which they were given to you, so that the medicine can be identified by the doctor or pharmacist at the hospital. Also tell them whether you have taken any other medicines.

Symptoms of excessive overdosage are restlessness, hallucinations, delirium, convulsion, circulatory failure, respiratory depression, paralysis of voluntary muscles and coma.

If you forgot to take Propantheline 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Propantheline 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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

5. HOW TO STORE PROPANTHELINE TABLETS

Keep this medicine out of the sight and reach of children.

Keep your medicine in a dry place and store below 25ºC. Keep container tightly closed.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Propantheline tablets contains
The active substance in each tablet is propantheline bromide 15 mg.
The other ingredients in the tablet are: lactose monohydarte, maize starch, pre-gelatinised starch, microcrystalline cellulose, colloidal anhydrous silica, ethylcellulose, magnesium stearate, hypromellose, diethylphthalate, PB-620004 Yellow (Titanium Dioxide, Quinoline Yellow Aluminium Lake, Hydroxypropyl Cellulose, Sunset Yellow FCF) and PB-630004 Orange (Titanium Dioxide, Hydroxypropyl Cellulose, Sunset Yellow FCF).

What Propantheline tablets looks like and contents of the pack
The tablets are round and convex in shape, and orange in colour.

They are available in containers of 100 and 112 tablets
Not all pack sizes ay be marketed

Marketing Authorisation Holder
Chelonia Healthcare Limited
Boumpoulinas 11, 3rd Floor,
Nicosia, P.C. 1060, Cyprus

Manufacturer
DDSA Pharmaceuticals Limited
84 Pembroke Road, W8 6NX, London

For more information about this product, please contact the Marketing Authorisation Holder.

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