

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Propantheline Tablets 15 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Propantheline Bromide BP 15.00 mg

Excipients with known effect: Lactose monohydrate (26.70 mg per tablet) and azo colouring agent sunset yellow FCF (E110) (Up to 0.252 mg per tablet).

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-Coated Tablets.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Adults:

- Hyperhidrosis
- Enuresis
- Adjunctive in GI disorders characterised by smooth muscle spasm

4.2 Posology and method of administration

Posology

Adults:

The recommended initial starting dose is one tablet before each meal and two tablets at bedtime. Subsequently dosage should be adjusted according to the patient's individual response and tolerance. Doses up to 120 mg may be required in some patients.

Elderly:

Elderly patients may be more susceptible to antimuscarinic side effects;

glaucoma and urinary retention may occur. Consideration should be given to the presence of other disease and concomitant drug therapy, (see contraindications, warnings etc).

Paediatric population:

Safety and efficacy of propantheline in children have not been established

Caution:

Food has been reported to reduce the bioavailability of propantheline. Tablets should be taken at least one hour before meals

Method of administration

Oral

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Propantheline is contra-indicated in patients with obstructive diseases of the gastrointestinal or urinary tract, pyloric stenosis, paralytic ileus, intestinal atony, severe ulcerative colitis or toxic megacolon, hiatus hernia associated with reflux oesophagitis, unstable cardiovascular adjustment in acute haemorrhage, myasthenia gravis, prostatic enlargement and in patients who are hypersensitive to propantheline bromide.

Propantheline should not be given to patients with close-angle glaucoma or those with shallow anterior chamber, since it may raise intra-ocular pressure.

4.4 Special warnings and precautions for use

In some patients, especially those with ileostomy or colostomy, diarrhoea may be a symptom of incomplete intestinal obstruction. Propantheline therapy should be avoided in such patients.

Patients with severe heart disease in whom an increase in heart rate is undesirable should be observed closely if Propantheline is administered.

Patients with ulcerative colitis should be treated with caution, since Propantheline may suppress intestinal motility to the point of producing paralytic ileus, thus precipitating or aggravating toxic megacolon.

Propantheline should be used with caution in the elderly and all patients with autonomic neuropathy, hepatic or renal disease, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias or hypertension.

Propantheline may induce fever and heat stroke in patients in a high environmental temperature due to decreased sweating.

Propantheline should be used with caution in patients with Down's syndrome.

Propantheline should also be used with caution in gastrointestinal reflux disease, acute myocardial infarction, cardiac insufficiency and pyrexia.

Propantheline Tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Since antimuscarinics tend to delay gastric emptying they may alter the absorption of other medication given concomitantly.

Analgesics: increased risk of antimuscarinic side effects when antimuscarinics are given with nefopam. The absorption of paracetamol has been reported to be reduced and retarded.

Anti-arrhythmics: increased risk of antimuscarinic side effects with disopyramide.

Antidepressants: increased risk of antimuscarinic side effects when antimuscarinics are given with MAOIs or tricyclics or tricyclic-related antidepressants.

Antifungals: antimuscarinics reduce absorption of ketoconazole.

Antihistamines: increased risk of antimuscarinic side effects when antimuscarinics are given with antihistamines.

Anti-infectives: the absorption of nitrofurantoin has been reported to be enhanced.

Antimuscarinics: Excessive muscarinic blockage may occur if Propantheline is given concomitantly with belladonna alkaloids, synthetic and semi-synthetic anticholinergic agents or other drugs with anticholinergic activity.

Antipsychotics: antimuscarinics possibly reduce effects of haloperidol; increased risk of antimuscarinic side effects when antimuscarinics are given with clozapine; antimuscarinics reduce plasma concentration of phenothiazines, but risk of antimuscarinic side effects is increased.

Digoxin: concurrent use of Propantheline with slow-dissolving tablets of digoxin may cause increased serum digoxin levels.

Domperidone: antimuscarinics antagonise effects of domperidone on gastrointestinal activity.

Dopaminergics: increased risk of antimuscarinic side effects when antimuscarinics are given with amantadine; antimuscarinics possibly reduce absorption of levodopa.

Memantine: effects of antimuscarinics possibly enhanced by memantine.

Metoclopramide: antimuscarinics antagonise effects of metoclopramide on gastrointestinal activity.

Nitrates: antimuscarinics possibly reduce effects of sublingual tablets of nitrates (failure to dissolve under tongue owing to dry mouth).

Parasympathomimetics; antimuscarinics antagonise effects of parasympathomimetics.

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal reproduction and teratology studies have not been performed.

Cohort data on parasympatholytics indicate a possible association with minor malformations. In view of this Propantheline should not be administered in pregnancy unless considered essential.

Breast-feeding

It is unknown whether Propantheline Bromide is excreted in human breast milk. No animal studies have been conducted. In view of this Propantheline should not be administered during breast-feeding unless considered essential. Suppression of lactation may occur with parasympatholytics.

4.7 Effects on ability to drive and use machines

Propantheline may produce drowsiness or blurred vision. Patients should not drive or operate machinery if affected in this way.

4.8 Undesirable effects

Side-effects of antimuscarinics include dryness of the mouth with difficulty in swallowing and thirst, dilation of the pupils with loss of accommodation and sensitivity to light, increased intra-ocular pressure, flushing, dryness of the skin, decreased sweating, heat stroke, bradycardia followed by tachycardia, palpitations and arrhythmias, urinary hesitancy and retention, constipation, reduced bronchial secretions, occasional confusion in the elderly, occasional nausea and vomiting, and occasional dizziness.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

Intensification of the usual side-effects may occur. In severe intoxication disturbances of the central nervous system may occur resulting in convulsion, coma, circulatory failure, respiratory depression, delirium, hallucinations and restlessness. Toxic doses of propantheline bromide may produce non-depolarising neuromuscular blocking effects with paralysis of voluntary muscle.

In the event of overdosage, empty the stomach and give activated charcoal. Excitement may be controlled by diazepam. Supportive treatment may require oxygen, assisted ventilation and the administration of fluids. In severe cases (convulsions, hyperpyrexia, respiratory depression) the use of intravenous physostigmine (0.5 to 2 mg) should be considered. Since it has a brief duration of action of 1 to 2 hours, it may be necessary to repeat injections up to a total dose of 5 mg.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Synthetic anticholinergics, quaternary ammonium compounds, ATC Code: A03AB05

Propantheline has anticholinergic pharmacological properties.

Propantheline inhibits parasympathetic activity by blocking the action of the neurohormone, acetylcholine, on the neuroeffector cell. This blocking action of Propantheline is instrumental in reducing gastric acid secretion and gastrointestinal motor activity.

5.2 Pharmacokinetic properties

Propantheline bromide is extensively metabolised in man. Some enzymic hydrolysis of the drug may occur in the gastrointestinal tract prior to its absorption.

Studies in healthy men demonstrated that peak plasma levels of unchanged drug were reached within 2 hours of a single oral dose of propantheline bromide. Following single oral dosing the plasma elimination half-life was about 2-3 hours and some 1-10% of propantheline bromide was excreted in urine as unchanged drug.

In healthy men studies have shown onset of antimuscarinic effects occurs within 1 hour of oral administration. Effects persisted for up to 6 hours after oral dosing.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in the other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize Starch
Pre-gelatinised Starch
Colloidal Anhydrous Silica
Magnesium stearate
Ethylcellulose 10 cps
Microcrystalline Cellulose
Hypromellose 5 cps
Hypromellose 15cps
Diethylphthalate
PB-620004 Yellow (Titanium Dioxide, Quinoline Yellow Aluminium Lake, Hydroxypropyl Cellulose and Sunset Yellow FCF Aluminum Lake/FD&C Yellow #6)
PB-630004 Orange (Titanium Dioxide, Hydroxypropyl Cellulose and Sunset Yellow FCF Aluminum Lake/FD&C Yellow #6)

6.2 Incompatibilities

None known.

6.3 Shelf life

48 Months

6.4 Special precautions for storage

Store in a dry place below 25°C.
Keep container securely closed.

6.5 Nature and contents of container

Pack sizes: 100 and 112 tablets

High-density polyethylene containers with polythene closures fitted with desiccant capsule insert within lid and sealed with a thick paper membrane.

Pack size: 112 tablets

High-density polyethylene containers with High-density polyethylene closures fitted with desiccant capsule insert within lid and sealed with a thick paper membrane.

6.6 Special precautions for disposal

No special instructions.

7 MARKETING AUTHORISATION HOLDER

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P.C.
1060
CYPRUS

8 MARKETING AUTHORISATION NUMBER(S)

PL 33414/0094

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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01/05/2026