

## PRESCRIBING INFORMATION

### Detrunorm 15 mg Coated Tablets & Detrunorm XL 30 mg Modified Release Capsules (propiverine hydrochloride)

**Presentation:** Coated tablets: Contain 15 mg propiverine hydrochloride. Capsules: Contain 30 mg propiverine hydrochloride in a modified-release preparation.

**Indication:** Tablets & capsules: Treatment of urinary incontinence, urgency and frequency in patients with idiopathic detrusor overactivity (overactive bladder).

Tablets only: Neurogenic detrusor overactivity (detrusor hyperreflexia) from spinal cord injuries, e.g. transverse lesion paraplegia.

**Dosage and administration:** Adults: Tablets: One 15 mg tablet twice a day, which may be increased to three times a day. Some patients may respond to one 15 mg tablet a day. For neurogenic detrusor overactivity: One 15 mg tablet three times a day; this may be increased to four times a day (maximum recommended daily dose). Capsules: One 30 mg capsule daily. Elderly: No special dosage regimen required. Children: Not to be used in this population due to a lack of data.

**Contraindications:** Hypersensitivity to any of the components. Obstruction of the bowel, significant degree of bladder outflow obstruction where urinary retention may be anticipated, myasthenia gravis, intestinal atony, severe ulcerative colitis, toxic megacolon, uncontrolled angle closure glaucoma, moderate or severe hepatic impairment and tachyarrhythmias.

**Warnings and precautions:** Use with caution in patients with autonomic neuropathy. Symptoms may be aggravated in: severe congestive heart failure (NYHA IV); prostatic hypertrophy; hiatus hernia with reflux oesophagitis; cardiac arrhythmia; tachycardia. Propiverine induces mydriasis hence the risk to induce acute angle-closure glaucoma in predisposed patients may be increased. Pollakiuria and nocturia due to renal disease, congestive heart failure or organic bladder diseases (e.g. urinary tract infection; malignancy) should be ruled out prior to treatment. The 15 mg tablet contains cochineal red A (E124, lake) which may cause allergic reactions. Both preparations contain lactose. Patients with rare

hereditary problems of galactose intolerance, the lapp lactose deficiency or glucose-galactose malabsorption should not take this medication.

**Pregnancy and lactation:** Should not be used during pregnancy or lactation.

**Interactions:** Tricyclic antidepressants, tranquillisers, anticholinergics, amantadine, neuroleptics, beta-adrenoceptor agonists, cholinergic drugs, isoniazid, prokinetics e.g. metoclopramide.

**Undesirable effects:** *Very common:* dry mouth. *Common:* accommodation disturbances, abnormal vision, constipation. *Uncommon:* fatigue, nausea, vomiting, dizziness, tremor, urinary retention, flushing, decreased blood pressure with drowsiness. All undesirable effects are transient and recede following dose reduction or termination. During long-term therapy hepatic enzymes should be monitored; reversible changes of liver enzymes might occur in rare cases. Monitoring of intraocular pressure is recommended in patients at risk of developing glaucoma. Attention should be paid to residual urine volume in cases of urinary tract infection. (Please refer to the Summary of Product Characteristics for detailed information)

**Overdose:** Central anticholinergic effects e.g. restlessness, dizziness, vertigo, speech/vision disorders, muscle weakness, severe dryness of mucosa, tachycardia and urinary retention.

**Legal category:** POM.

**Pack sizes and basic NHS prices:** *Tablets:* £18.00 for 56 x 15 mg tablets; *Capsules:* £24.45 for 28 x30 mg modified-release capsules.

**Marketing Authorisation Numbers:** PL 20072/0015; PL 20072/0016.

**Marketing Authorisation Holder:** Amdipharm Mercury Company Limited (AMCo), 1<sup>st</sup> Floor, Capital House, 85 King William Street, London, EC4N 7BL.

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**Date of revision:** December 2013

Adverse events should be reported to the local regulatory authority.

Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

Adverse events should also be reported to **Amdipharm Mercury Medical Information** via telephone on **08700 70 30 33** or via e-mail at [medicalinformation@amcolimited.com](mailto:medicalinformation@amcolimited.com).