

PRESCRIBING INFORMATION
Detrunorm XL 30mg and 45 mg Modified-Release Capsules
(Propiverine hydrochloride)

Presentation: Each capsule contains 30mg or 45mg propiverine hydrochloride in a modified-release preparation.

Indication: 30mg: Symptomatic treatment of urinary incontinence and/or increased urinary frequency and urgency in patients with overactive bladder syndrome. 45mg: Symptomatic treatment of urinary incontinence and/or increased urinary frequency and urgency in patients with overactive bladder syndrome or neurogenic detrusor overactivity (detrusor hyperreflexia) from spinal cord injuries.

Dosage and administration: For oral administration. 30mg: One capsule daily. 45mg: One capsule daily. *Elderly*: No special dosage regimen required. *Children*: Not to be used in this population due to a lack of data. *Renal impairment*: 45mg capsule not recommended in severe renal impairment.

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.

Precautions and warnings: Use with caution in patients with autonomic neuropathy, renal or hepatic impairment. 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. Contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medication.

Interactions: Tricyclic antidepressants, tranquillisers, anticholinergics, amantadine, neuroleptics, beta-adrenoceptor agonists, cholinergic drugs, isoniazid, prokinetics e.g. metoclopramide. Propiverine may be considered a weak inhibitor of cytochrome P450 3A4 so other pharmacokinetic interactions are possible with drugs metabolised by this system.

Fertility, pregnancy and lactation: Should not be used during pregnancy or lactation.

Undesirable effects: *Very common*: dry mouth. *Common*: accommodation disturbances, abnormal vision, headaches, constipation, abdominal pain, dyspepsia, fatigue. 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: 30mg: £24.45 for 28 capsules; 45mg: £27.00 for 28 capsules

Marketing Authorisation Numbers: 30mg: PL 20072/0016; 45mg: PL 20072/0218

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

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Adverse events should be reported to the local regulatory authority. Reporting forms and information can be found at 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.