

DETRUNORM 15 MG COATED TABLETS

DETRUNORM XL 30 MG MODIFIED RELEASE CAPSULES

Abbreviated prescribing information

Refer to Summary of Product Characteristics before prescribing. **Presentations:** Coated tablets containing 15 mg of propiverine hydrochloride. Modified release capsules containing 30 mg of propiverine hydrochloride. **Indications:** Treatment of urinary incontinence, urgency and frequency in patients with idiopathic detrusor overactivity (overactive bladder) (tablets and capsules) or neurogenic detrusor overactivity (detrusor hyperreflexia) from spinal cord injuries, e.g. transverse lesion paraplegia (tablets). **Dosage and administration:** Recommended daily doses: *15mg Tablets:* Adults and elderly: 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; *30mg Capsules:* One 30 mg capsule once a day. For neurogenic detrusor overactivity the recommended dose is one 15 mg tablet three times a day; this may be increased to four times a day (maximum recommended daily dose). There is no clinically relevant effect of food on the pharmacokinetics of propiverine. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients and patients suffering from: 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; tachyarrhythmias. **Warnings etc:** Detrunorm should be used 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 hydrochloride, like other anticholinergics, induces mydriasis; therefore, the risk to induce acute angle-closure glaucoma 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. Due to lack of data Detrunorm should not be used in children. **Interactions:** tricyclic antidepressants, tranquillisers, anticholinergics, amantadine, neuroleptics, beta-adrenoceptor agonists, cholinergic drugs, isoniazid, prokinetics e.g. metoclopramide. **Pregnancy, lactation:** Detrunorm should not be used during pregnancy or by nursing women. **Driving, operating machinery:** Detrunorm may impair the ability to exert activities that require mental alertness such as driving a motor vehicle or operating machinery. **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. Rare: rash due to idiosyncrasy (propiverine hydrochloride) or hypersensitivity (excipients). Very rare: palpitation, restlessness, confusion. All undesirable effects are transient and recede after maximum 1-4 days 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. **Legal category:** POM. **Marketing authorisation numbers:** Detrunorm 15 mg Coated Tablets PL 20072/0015; Detrunorm XL 30 mg Modified Release Capsules PL 20072/0016. **Marketing authorisation holder:** Amdipharm plc, Regency House, Miles Gray Road, Basildon, Essex. SS14 3AF, UK. **Basic nhs price:** Detrunorm 15 mg Coated Tablets - blister packs containing 56 tablets £18.00. Detrunorm XL 30 mg Modified Release Capsules - blister packs containing 28 capsules £24.45. Further information is available from Amdipharm, Regency House, Miles Gray Road, Basildon, Essex SS14 3AF. E-mail: medinfo@amdipharm.com. **Date of preparation:** June 2010 (100618DT122).