

Regurin XL 60mg Prescribing information

Read the SPC before prescribing. Prolonged release capsules, hard, containing 60 mg of trospium chloride.

Indication: Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder.

Dosage and administration: One capsule once daily (equivalent to 60 mg of trospium chloride per day). Regurin XL 60 mg should be taken with water on an empty stomach one hour before a meal.

Contra-indications: Trospium chloride is contraindicated in patients with urinary retention, severe gastro-intestinal conditions (including toxic megacolon), myasthenia gravis, narrow-angle glaucoma, and tachyarrhythmia. Trospium chloride is also contraindicated in patients who have demonstrated hypersensitivity to the active substance or to any of the excipients. Precautions: Trospium chloride should be used with caution by patients with obstructive conditions of the gastrointestinal tract such as pyloric stenosis, with obstruction of the urinary flow with the risk of formation of urinary retention, with autonomic neuropathy, with hiatus hernia associated with reflux oesophagitis and in whom fast heart rates are undesirable e.g. those with hyperthyroidism, coronary artery disease and congestive heart failure. Regurin XL 60 mg should not be given to patients with severe hepatic impairment and caution should be exercised in patients with mild to moderate liver impairment. Regurin XL 60 mg is not recommended for renally impaired patients. Before commencing therapy organic causes of urinary frequency, urgency, and urge incontinence, such as heart disease, renal disease, polydipsia, or infections, or tumours of urinary organs should be excluded.

Interactions: Potentiation of the effect of

medicinal products with anticholinergic action (such as amantadine, tricyclic antidepressants), enhancement of the tachycardic action of β -sympathomimetics; decrease in efficacy of pro-kinetic agents (e.g. metoclopramide).

Pregnancy and lactation: Clinical data on exposure during pregnancy or lactation are not available for Regurin XL 60 mg. Caution should be exercised when prescribing to pregnant or breastfeeding women.

Side-effects: Dry mouth is very common (>10%). Common (<10%) Dry eye, dyspepsia, constipation, constipation aggravated, abdominal pain, abdominal distension, nausea and nasal dryness; uncommon (<1%) flatulence; rare (<0.1%) tachycardia, vision disturbance, asthenia, micturition disorders, urinary retention and rash. For other very rare side effects, please see the Regurin XL SPC.

Presentations and basic NHS prices: Regurin XL packs contain 28 prolonged release capsules. Each capsule contains 60mg of trospium chloride. £23.05. MA Number: PL 46302/0194

Legal category: POM

Marketing Authorisation Holder: Mylan Products Ltd., Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

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Further information available on request from Contura Ltd, 14 Took's Court, London EC4A 1LB
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Adverse events: Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Contura Ltd. (Telephone 01707 853 000).