

**Blerone XL 4mg prolonged release capsules (tolterodine tartrate) Prescribing Information. Prescribers should consult the SmPC before prescribing.**

**Presentation:** Each Blerone XL 4mg prolonged release capsule contains 4mg of tolterodine tartrate, equivalent to 2.74mg of tolterodine.

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

**Dosage and administration: Adults (including elderly):** 4mg once daily, reduce to 2mg in case of troublesome side-effects. Re-evaluate effect of treatment after 2-3 months.

**Special Populations: Paediatric population:** Not recommended. Patients with impaired liver function or severely impaired renal function (GFR  $\leq$  30ml/min): 2mg once daily.

**Method of administration:** can be taken with or without food and must be swallowed whole.

**Fertility, pregnancy and lactation:** Not recommended during pregnancy and lactation. No data from fertility studies is available.

**Contraindications:** Hypersensitivity to the active substance or to any of the excipients, urinary retention, uncontrolled narrow angle glaucoma, myasthenia gravis, severe ulcerative colitis, toxic megacolon.

**Special warnings and precautions:** Use with caution in patients with: significant bladder outlet obstruction at risk of urinary retention, gastrointestinal obstructive disorders, e.g. pyloric stenosis, renal impairment, hepatic disease, autonomic neuropathy, hiatus hernia, risk of decreased gastrointestinal motility, diabetes mellitus, congenital or documented acquired QT prolongation, electrolyte disturbances such as hypokalaemia, hypomagnesaemia and hypocalcaemia, bradycardia, cardiomyopathy, myocardial ischaemia, arrhythmia, congestive heart failure, when co-administered with medicines known to prolong QT-interval e.g. quinidine, procainamide, amiodarone, sotalol, anti-arrhythmics. Avoid concomitant treatment with potent CYP3A4 inhibitors. Contains lactose: patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take.

**Drug interactions:** Potent CYP3A4 inhibitors such as macrolide antibiotics (erythromycin and clarithromycin), antifungal agents (ketoconazole, itraconazole) and antiproteases, other antimuscarinic drugs, muscarinic cholinergic receptor agonists, prokinetics (e.g. metoclopramide and cisapride), cholinesterase inhibitors.

**Effects on ability to drive/use machines:** may cause accommodation disturbances and influence reaction time, therefore ability to drive and use machines may be negatively affected.

eyes, abnormal vision (including abnormal accommodation), cardiac failure, arrhythmia, tachycardia dry mouth, dyspepsia, constipation, abdominal pain, flatulence, diarrhoea, angioedema, dysuria, urinary retention, fatigue, peripheral oedema, chest pain.

**Pack size and UK list price:** Blerone XL 4mg prolonged release capsules (PL 17780/0629), pack size: 28, £ 6.90 .

**Legal Category:** POM.

**Marketing Authorisation Holder:** Zentiva Pharma UK Limited, 12 New Fetter Lane, London ECA 1JP, UK

**Date of preparation:** 24 Mar 2023 **Ref:** 000579194

**Adverse events should be reported. 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 Zentiva via email to [PV-United-Kingdom@zentiva.com](mailto:PV-United-Kingdom@zentiva.com) or via phone on 0800 090 2408.**