



NEDITOL® XL (tolterodine) 2mg and 4mg PRICE GUARANTEE

Our mission is to work with the NHS to help achieve their efficiency savings goals by offering high quality branded medicines that provide significant cost savings and continuity for patients.*

The NEDITOL XL range could save the NHS 50% on their current costs compared to the current Category C Drug tariff price for tolterodine 4mg prolonged-release capsules.^{1**}

Product	Category C Drug Tariff Price ¹	Neditol XL
Tolterodine prolonged-release capsules 4mg x28	£25.78	£12.89
Tolterodine prolonged-release capsules 2mg x28	£11.60	£11.60

We confirm that the prices will remain unchanged unless there is a material change to Category C of the UK Drug tariff or the product in the 2024 PPRS review.

If you would like any further information, please do not hesitate to contact Aspire Pharma on 01730 231148 or info@aspirepharma.co.uk.

Yours sincerely

A handwritten signature in black ink, appearing to read "Richard Condon".

Richard Condon
Chief Executive Officer

* Ensuring continuity by guaranteeing a single product is dispensed, rather than patients being dispensed a variety of generic products.

** 50% saving on the cost of Category C tolterodine 4mg prolonged-release capsules in the UK Drug Tariff.

References: 1) May 2022 UK Drug Tariff.

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NEDITOL XL (Tolterodine) Prolonged-release Capsules Prescribing Information (please refer to the full SmPC before prescribing)

Indications: Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome. **Available strengths:** 2mg and 4mg x 28 prolonged-release capsules. **Dosage and method of use:** 4mg once daily except in patients with impaired liver or kidney function for whom recommended dose is 2mg once daily. In case of troublesome adverse reactions dose may be reduced from 4mg to 2mg once daily. Effect of treatment should be re-evaluated after 2-3 months. Take capsules with or without food and swallow whole. Not recommended for children. **Contraindications:** Hypersensitivity to the active substance or any excipient, urinary retention, uncontrolled narrow angle glaucoma, myasthenia gravis, severe ulcerative colitis, toxic megacolon. **Special warnings and precautions for use:** Use with caution in patients with significant bladder outlet obstruction at risk of urinary retention, gastrointestinal obstructive disorders, renal impairment, hepatic disease, autonomic neuropathy, hiatus hernia, at risk of decreased gastrointestinal motility, risk factors for QT prolongation including: congenital or documented acquired QT prolongation, electrolyte disturbances such as hypokalaemia, hypomagnesaemia and hypocalcaemia, bradycardia, relevant pre-existing cardiac diseases, concomitant administration of drugs known to prolong QT-interval including Class IA and Class III anti-arrhythmics. Avoid concomitant treatment with potent CYP3A4 inhibitors. Consider organic reasons for urge and frequency before treatment. Capsules contain lactose and sodium. Patients with rare hereditary problems of galactose intolerance, the total lactase deficiency

or glucose-galactose malabsorption should not take this medicine. Concomitant treatment with other drugs possessing antimuscarinic properties may result in more pronounced therapeutic effect and side effects. Conversely, therapeutic effect of tolterodine may be reduced by concomitant administration of muscarinic cholinergic receptor agonist. Effect of prokinetics like metoclopramide and cisapride may be decreased by tolterodine. As may cause accommodation disturbances and influence reaction time, ability to drive/ use machines may be negatively affected. **Pregnancy/lactation:** Not recommended during pregnancy; avoid during lactation. **Side effects:** For the full list of side effects consult SmPC. 'Very Common' 'Common' and 'Serious' side effects included. Very common ($\geq 1/10$): dry mouth; Common ($\geq 1/100$ to $< 1/10$): sinusitis, dizziness, somnolence, headache, dry eyes, abnormal vision (including abnormal accommodation), dyspepsia, constipation, abdominal pain, flatulence, diarrhoea, dysuria, fatigue, peripheral oedema. Serious Uncommon ($\geq 1/1000$ to $< 1/100$): hypersensitivity, cardiac failure, arrhythmia, urinary retention. Serious (unknown frequency): anaphylactoid reactions, tachycardia, angioedema. Cases of aggravation of symptoms of dementia have been reported after tolterodine therapy was initiated in patients taking cholinesterase inhibitors for treatment of dementia. **MA number:** PL 35533/0148-0149 **Cost** £12.89 for 4mg x 28, £11.60 for 2mg x 28. **MAH:** Aspire Pharma Ltd, Unit 4, Rotherbrook Court, Bedford Road, Petersfield, Hampshire GU32 3QG. **Legal category:** POM. **Date last reviewed:** April 2021. **Version number:** 1010083024 v 6.0

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Aspire Pharma Ltd on 01730 231148.

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