Detrusitol®XL. Abbreviated Prescribing Information. Presentation: 4mg prolonged release capsule: blue with white printing (symbol and 4) containing tolterodine tartrate corresponding to 2.74mg tolterodine. **Indication** Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome. **Dosage:** Adults (including the elderly): 4mg od except in patients with impaired liver function or severely impaired renal function for whom the recommended dosage is 2mg daily. For troublesome side effects the dose may be reduced from 4mg to 2mg daily*. Review treatment after 2-3 months. Children: Not recommended. **Contraindications:** Patients with urinary retention, uncontrolled narrow angle glaucoma, myasthenia gravis, known hypersensitivity to tolterodine or excipients, severe ulcerative colitis or toxic megacolon. **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, risk of decreased gastrointestinal motility, renal impairment and hepatic disease (see dosage), autonomic neuropathy or hiatus hernia, risk factors for QT prolongation, relevant pre-existing cardiac diseases or concomitant administration of Class IA and Class III anti-arrhythmics. Organic reasons for urge and frequency should be considered before treatment. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. **Drug Interactions:** Concomitant treatment with potent CYP3A4 inhibitors, such as macrolide antibiotics, antifungal agents or antiproteases should be avoided. A more pronounced therapeutic effect and side effects may be seen if used with other drugs that possess antimuscarinic properties. Muscarinic cholinergic receptor agonists may reduce the effect of tolterodine, whereas tolterodine may reduce the effect of metoclopramide and cisapride. Drug interaction studies have shown no interactions with warfarin or combined oral contraceptives (ethinyloestradiol/levonorgestrel). No clinically significant interaction with fluoxetine. **Pregnancy & lactation:** Until more information is available tolterodine should not be used during pregnancy or lactation. **Side effects:** Those reported include: *common* (≥1/100, ≤1/10) dry mouth, sinusitis, dyspepsia, constipation, abdominal pain, flatulence, diarrhoea, dysuria, headache, dry eyes, abnormal vision (including abnormal accommodation), somnolence, dizziness, fatigue and peripheral oedema; *uncommon* (≥1/1000, ≤1/100) urinary retention, hypersensitivity not otherwise specified nervousness, paresthesia, memory impairment, vertigo, palpitations, cardiac failure, arrhythmia, chest pain; *not known* anaphylactoid reactions, confusion, disorientation, tachycardia, flushing, gastroesphageal reflux, vomiting, angioedema, dry skin and hallucinations. Aggravation of symptoms of dementia has been reported after initiation in patients taking cholinesterase inhibitors to treat dementia. In two paediatric studies the proportion of patients with urinary tract infections, diarrhoea and abnormal behaviour was higher in patients treated with tolterodine than placebo. **Driving and operating machinery:** The ability to drive and use machines may be affected by accommodation disturbances and reaction time. **Overdose:** In the event of tolterodine overdose, treat with gastric lavage and give activated charcoal. Treat symptomatically. **Legal category:** POM. **Pack sizes:** Detrusitol®XL 4mg in cartons of 28 containing 2 blister strips of 14 capsules each; **NHS price:** Detrusitol®XL 4mg (28) £25.78. **Marketing authorisation numbers:** Detrusitol®XL 4mg prolonged release capsules PL 00057/0968 **Marketing authorisation holder:** Pfizer Limited, Ramsgate

Road, Sandwich, Kent, CT13 9NJ UK. * currently available in 1mg bd presentation. Date last revised: 05/2012

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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 Pfizer Medical Information on 01304 616161.

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