Chief Medical Officer Directorate Pharmacy and Medicines Division



27 May 2025

# Medicine Supply Alert Notice

## Tolterodine 2mg and 4mg modified-release capsules

# Priority: Level 2<sup>\*</sup> Valid until: mid-September 2025

#### Issue

- 1. Tolterodine 2mg and 4mg modified-release (MR) capsules are in limited supply until mid-August and mid-September 2025, respectively.
- 2. Tolterodine 1mg and 2mg immediate release (IR) tablets remain available and can support increased demand.
- 3. Alternative once-daily antimuscarinics also remain available and can support increased demand.
- 4. Unlicensed imports of tolterodine MR capsules may be sourced; lead times vary.

## **Advice and Actions**

- 5. Prescribers should not initiate new patients on tolterodine MR capsules until the supply issues have resolved.
- 6. Review patients and the ongoing need for antimuscarinic treatment. Where ongoing treatment is appropriate, and patients have insufficient supplies to last until the resupply date, clinicians should consider prescribing:
  - tolterodine IR tablets, ensuring the patient is counselled on the new dose and frequency (see Additional information section); or
  - an alternative once-daily antimuscarinic (see Additional information section); or
  - unlicensed tolterodine MR capsules where the above options are not appropriate (see Additional information section).

## **Additional Information**

#### Clinical Information

- 7. Tolterodine is indicated for the treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome. It is licensed for use in adults, and is used off-label in children.
- 8. The MR preparations may be associated with a lower rate of dry mouth than IR preparations. The dose of MR preparations is 4mg once daily except in patients with impaired liver function or

\*https://www.nss.nhs.scot/media/1842/medicine-supply-alert-notices-definitions-of-classifications-21-october-2019.pdf severely impaired renal function, or in case of troublesome side-effects, where the dose is 2mg once daily. When switching to an IR preparation, the total daily dose is the same but it is administered in two divided doses, and in case of side effects, dose adjustment may be required.

9. Other once-daily antimuscarinics are an option for patients unable to tolerate IR tolterodine or adhere to its twice daily dose regimen. These include oxybutynin MR, solifenacin, trospium MR, darifenacin, fesoterodine, and propiverine MR. Individual SmPCs should be consulted for indications, cautions, contraindications and excipients, as these may vary between products.

## Links to further information

- <u>SmPC Tolterodine</u>
- BNF Tolterodine
- BNFC Tolterodine
- BNF Oxybutynin
- BNF Solifenacin
- BNF Trospium
- BNF Darifenacin
- BNF Fesoterodine
- BNF Propiverine
- BNF treatment summary: Lower urinary tract symptoms in males
- BNF treatment summary: Urinary incontinence and pelvic organ prolapse in women
- BNFC treatment summary: Urinary frequency, enuresis and incontinence
- <u>NICE CKS: Incontinence urinary, in women</u>
- NICE CKS: LUTS in men

#### Guidance on ordering and prescribing unlicensed medicines

- 10. The following Specialist Importers have confirmed they can source unlicensed tolterodine 2mg and 4mg MR capsules. Please note there may be other companies that can also source supplies:
  - Chemys Ltd
  - Target Healthcare
- 11. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Health Board or local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes. Please see the links below for further information:
  - <u>The supply of unlicensed medicinal products</u>, Medicines and Healthcare products Regulatory Agency (MHRA)
  - <u>Professional Guidance for the Procurement and Supply of Specials</u>, Royal Pharmaceutical Society
  - <u>Prescribing unlicensed medicines</u>, General Medical Council (GMC).

## Specialist Pharmacy Service (SPS) website

- 12. The UK Department of Health and Social Care (DHSC) in conjunction with the Specialist Pharmacy Service (SPS) have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues. To access the online Medicines Supply Tool you need to register with the <u>SPS website</u>. Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.
- 13. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

## Enquiries

14. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to <a href="mailto:PharmacyTeam@gov.scot">PharmacyTeam@gov.scot</a> (primary care) or <a href="mailto:NSS.NHSSMedicineShortages@nhs.scot">NSS.NHSSMedicineShortages@nhs.scot</a> (secondary care).