



25 July 2023

## **Medicine Supply Alert Notice**

### **Atomoxetine 40mg and 60mg capsules**

**Priority: Level 2\***

**Valid until: September 2023**

#### **Issue**

1. Atomoxetine 40mg and 60mg capsules will be out of stock from late July 2023 until September 2023.
2. Other strengths and formulations of atomoxetine remain available but in insufficient quantities to meet increased demand.
3. Guanfacine (Intuniv<sup>®</sup>) prolonged release tablets remain available.
4. For information on the availability of methylphenidate prolonged release tablets, please refer to the Specialist Pharmacist Service (SPS) [Medicine Supply Tool](#). (see paragraph 16 of how to access the Medicine Supply Tool).
5. Unlicensed supplies of atomoxetine 40mg and 60mg capsules may be sourced, lead times vary.

#### **Advice and Actions**

6. Healthcare professionals / prescribers in primary and secondary care should:
  - proactively identify any patients on atomoxetine 40mg and 60mg capsules;
  - contact patients to establish how much supply they have left; and
  - liaise with the patient's specialist team for advice on management options.
7. Specialist teams should:
  - ensure no new patients are initiated on atomoxetine capsules until the shortage is resolved;
  - support primary care clinicians seeking advice for patients currently taking atomoxetine 40mg and 60mg capsules, including provision of individualised management plans, where required; and
  - offer alternatives in line with [NICE ADHD guidance NG87](#) where required.
8. Where the above options are not considered appropriate, supplies of unlicensed atomoxetine 40mg and 60mg capsules may be sourced. Contact should be made with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see additional information below).

## Additional Information

### Clinical Information

9. Stimulants such as lisdexamfetamine or methylphenidate are recommended first-line treatments for attention deficit hyperactivity disorder (ADHD). Treatment with non-stimulants (e.g. atomoxetine or guanfacine) are an option in patients who are intolerant to both methylphenidate and lisdexamfetamine, or who have not responded to separate 6-week trials of both drugs ([NICE ADHD guidance NG87](#)). These treatments must be initiated by a specialist in the treatment of ADHD.
10. Atomoxetine selectively inhibits pre-synaptic noradrenaline reuptake and is licensed for the treatment of ADHD in children aged 6 years and older, in adolescents, and in adults. In the paediatric population up to 70 kg body weight, atomoxetine should be initiated at a total daily dose of approximately 0.5 mg/kg and dose titrated upwards after a minimum of 7 days according to clinical response and tolerability. The recommended maintenance dose is approximately 1.2 mg/kg/day. For paediatric population over 70 kg, the initial dose is 40mg for minimum of 7 days followed by upwards dose titration. The recommended maintenance dose is 80mg. In adults, atomoxetine is initiated at 40 mg for a minimum of 7 days prior to upward dose titration and the recommended maintenance daily dose is 80 mg to 100 mg.
11. Guanfacine, a selective alpha<sub>2A</sub>-adrenergic receptor agonist, is licensed for the treatment of ADHD in children and adolescents aged 6-17 years for whom stimulants are not suitable, not tolerated or have been shown to be ineffective.
12. Patients on atomoxetine should be periodically reviewed in line with [NICE](#) guidance.

### Guidance on ordering and prescribing unlicensed imports

13. The following specialist importers have confirmed they can source unlicensed atomoxetine 40mg and 60mg capsules (please note there may be other companies that can also source supplies):
  - Alium
  - BAP Pharma
  - Qmed Pharma
  - Target
14. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Board or local governance procedures. Please see the links below for further information:
  - [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
  - [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society
  - [Prescribing unlicensed medicines](#), General Medical Council (GMC)

### Refer to the links below for further information

- [Atomoxetine capsules SmPC](#)
- [BNF: Attention deficit hyperactivity disorder](#)
- [NICE guideline \[NG87\]: Attention deficit hyperactivity disorder: diagnosis and management](#)
- [Guanfacine \(Intuniv®\) prolonged release tablets SmPC](#)

## **Specialist Pharmacy Service (SPS) website**

15. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues.
16. To access the online Medicines Supply Tool you need to register with the [SPS website](#). 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.
17. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool in order to stay up to date concerning medicines supply disruptions.
18. 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**

19. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to [PharmacyTeam@gov.scot](mailto:PharmacyTeam@gov.scot) (primary care) or [NSS.NHSSMedicineShortages@nhs.scot](mailto:NSS.NHSSMedicineShortages@nhs.scot) (secondary care).