



26 June 2020

## **Medicine Supply Alert Notice**

### **Mirtazapine 15mg and 45mg orodispersible tablets**

**Priority: Level 2\***

**Valid until: Late July 2020**

#### **Issue**

1. Mirtazapine 15mg and 45mg orodispersible tablets are out of stock until late July 2020.
2. Unlicensed imports of mirtazapine orodispersible tablets have been sourced.
3. Mirtazapine 30mg orodispersible tablets remain available but cannot support any increase in demand.
4. Mirtazapine 15mg, 30mg and 45mg tablets remain available.
5. Mirtazapine 15mg/ml oral suspension remains available but cannot support any increase in demand.

#### **Advice and Actions**

6. Where the patient has insufficient supplies to last until the resupply date and following discussion with the patient/carer, clinicians should:
  - review ongoing need for mirtazapine; and
  - clarify the rationale for drug and formulation choice.
7. Following the above, clinicians should then consider:
  - prescribing mirtazapine tablets where the formulation is not critical (see additional information below);
  - prescribing an unlicensed import of mirtazapine orodispersible tablets where standard tablets are not appropriate, and drug and formulation is critical; and
  - switching to an alternative antidepressant which is available in a suitable formulation using national and local guidelines, in patients who are unable to swallow tablets.
8. Where the above options are not appropriate and where mirtazapine orodispersible tablets are considered to be uniquely indicated or where they have been recommended/initiated by a specialist, clinicians should consider seeking advice/re-referral to a specialist for alternative medication choices and strategies for switching patients in primary care.
9. In addition to the above, clinicians in health and justice settings should consider collaborating with custodial leads to support extra vigilance needed to reduce the risk of diversion during supervised administration of the tablet formulation.

#### **Additional Information**

10. Standard mirtazapine tablets should be swallowed whole, however, if patients cannot swallow tablets, cannot access other formulations of mirtazapine and an alternative antidepressant is not appropriate, NEWT guidelines advise the tablets could be crushed (considered unlicensed). It should be noted that the tablet has a bitter taste and an anaesthetic effect on the mouth.

11. The following specialist importers have currently confirmed they can source unlicensed mirtazapine orodispersible tablets with variable lead times (please note, there may be other companies that can also source supplies):
- Alium Medical;
  - Target Healthcare.
12. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and/or local governance procedures. Please see the links below for further information:
- [Prescribing unlicensed medicines](#), General Medical Council (GMC);
  - [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.

### **Enquiries**

13. 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.net](mailto:NSS.NHSSMedicineShortages@nhs.net) (secondary care).