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Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
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Medicine Supply Alert Notice

Methylphenidate prolonged-release tablets

Priority: Level 3*
Valid until: October 2024

Issue

1. Methylphenidate prolonged-release tablet brands are in limited supply and intermittent regional supply disruptions are expected to continue until October 2024.
2. Lisdexamfetamine (Elvanse®, Elvanse Adult®) capsules remain available and can support increased demand.
3. Prescribed Elvanse® and Elvanse Adult® capsules generically until normal methylphenidate prolonged release tablet supply resumes.
4. Methylphenidate (Equasym® XL) modified-release capsules remain available but **cannot** support increased demand.
5. Unlicensed supplies of methylphenidate prolonged-release tablets can be sourced, lead times vary.

Advice and Actions

6. Specialist teams should:
   - consider pausing new patient initiations on all methylphenidate prolonged-release tablet brands until normal supply resumes;
   - as lisdexamfetamine capsules remain available, consider appropriateness of prescribing as a first line alternative in adults, if a treatment is required before normal supply of methylphenidate prolonged-release tablets resume;
   - prescribe Elvanse® and Elvanse Adult® capsules generically;
   - for children and young people consider offering other clinically appropriate and available options (pharmacological and non-pharmacological) in line with NICE guidance in order to avoid undue delays in initiating treatment, and
   - offer rapid response to primary care teams seeking urgent advice/opinion for the management of patients with ADHD, narcolepsy and idiopathic hypersomnia. This includes those known to be at a higher risk of adverse impact due to these supply disruptions, e.g. those with complex presentations including co-morbid autism, mental health or substance misuse needs.

7. For patients currently prescribed methylphenidate prolonged-release tablets, clinicians should:

***https://www.nss.nhs.scot/media/1842/medicine-supply-alert-notices-definitions-of-classifications-21-october-2019.pdf**

- consider prescribing alternative clinically equivalent available brands of methylphenidate prolonged-release tablets ensuring that the patient is not intolerant to any of the excipients;
- inform patients switched to another brand of methylphenidate prolonged-release tablets of any difference in release profile, counselling them on any change in administration requirements (see Additional Information section); and to report any changes in symptoms or side effects after switching;
- review the patient post switch and reassure them that any changes to their prescription will be short-term and for the duration of the supply issue only, and they have the option to switch back to their original brand once the supply issue is resolved;
- ensure methylphenidate prolonged-release tablets are prescribed on a separate prescription (GP10) which should not be sent to a nominated pharmacy unless the medicine is confirmed to be in stock at that pharmacy (see Additional Information); and
- if the above options are not considered appropriate, advice should be sought from specialists on other clinically appropriate options (pharmacological and non-pharmacological) in line with NICE guidance to avoid potentially disruptive breaks in treatment if methylphenidate is unavailable.

Additional Information

Clinical Information

Methylphenidate

8. Methylphenidate, a central nervous system stimulant, is licensed for the treatment of attention deficit hyperactivity disorder (ADHD) and is a first line treatment option for this condition. It is available as immediate release tablets and as modified-release tablets and capsules.
9. The modified-release methylphenidate preparations include an immediate-release (IR) and an extended-release (ER) component, allowing a two-phase release of drug. The proportions of IR and MR methylphenidate differs between brands and different products may not therefore have the same clinical effect.
10. The MHRA advises caution if switching patients between different long-acting formulations of methylphenidate due to the differences in dosing frequency, administration with food, amount and timing of the modified-release component, and overall clinical effect. For these reasons, the products are usually prescribed by brand name.

Lisdexamfetamine

11. This central nervous system stimulant is a prodrug hydrolysed to dexamfetamine. It is licensed for treatment of ADHD in children aged 6 years and over when response to previous methylphenidate treatment is considered clinically inadequate, and also in adults with pre-existing symptoms of ADHD in childhood. The licensed dose ranges from 20mg to maximum of 70mg once daily.
12. NICE guidance recommends methylphenidate or lisdexamfetamine as a first-line pharmacological treatment option for adults with ADHD. When lisdexamfetamine is used for extended periods (over 12 months) its usefulness should be re-evaluated at least yearly, and consideration given to trial periods off medication to assess the patient's functioning without pharmacotherapy. It recommends methylphenidate (either short or long acting) as the first line pharmacological treatment for children aged 5 years and over and young people with ADHD.

Further guidance

13. Prescribing teams should routinely check the Medicines Supply Tool, located on the Specialist Pharmacist Service (SPS) website, for up-to-date information on resupply dates for methylphenidate presentations. This information is collated by the UK Government's Department of Health and Social Care (DHSC). To gain access to the noted medicines supply tool, healthcare professionals will need first to register their details on the SPS website.
14. Further guidance on the pharmacokinetic differences between modified-release methylphenidate products and clinical implications can be found on the SPS page 'Considerations when prescribing modified-release methylphenidate'. A list of currently available and unavailable medicines used to treat ADHD can also be found on the SPS 'Prescribing available medicines to treat ADHD' page.

Links to further information

- Concerta® XL prolonged-release tablets SmPC
- Delmosart® prolonged-release tablets SmPC
- Matoride® XL prolonged-release tablets SmPC
- Xaggitin® XL prolonged-release tablets SmPC
- Xenidate® XL prolonged-release tablets SmPC
- Affenid® XL prolonged-release tablets SmPC
- Elvanse hard capsules SmPC
- NICE guideline for attention deficit hyperactivity disorder
- Considerations when prescribing modified-release methylphenidate – SPS
- Supporting system response to the ADHD medicine shortage – SPS
- Prescribing available medicines to treat ADHD - SPS

Guidance on ordering and prescribing unlicensed imports

15. The following specialist importers have confirmed they can source unlicensed methylphenidate prolonged-release tablets (please note there may be other companies that can also source supplies):
    - Alium (2-3 weeks lead time)
    - Mawdsleys (3-4 weeks lead time)
    - SmartWay (4-6 weeks lead time)
    - Target Healthcare (1-2 weeks lead time)

16. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and 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:
    - 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).

Specialist Pharmacy Service (SPS) website

17. 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. 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.
18. 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

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