NHS Circular:
MSAN (2024) 20

Chief Medical Officer Directorate
Pharmacy and Medicines Division

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Riaghaltas na h-Alba
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# Medicine Supply Alert Notice

## Lisdexamfetamine (Elvanse®) capsules

## Priority: Level 3*
## Valid until: August 2024

### Issue

1. All strengths of Elvanse® capsules are now available and an improved level of supply will continue across the majority of Elvanse® and Elvanse Adult® presentations.
2. There will however be intermittent supply issues with Elvanse® 40mg, Elvanse® Adult 40mg and Elvanse® 60mg capsules until August 2024.
3. Elvanse® 20mg capsules remain available, **but cannot support an increase in demand** during shortages of Elvanse® 40mg, Elvanse® Adult 40mg and Elvanse® 60mg capsules.
4. Elvanse® 30mg capsules remain available and can support an increase in demand during the shortage of Elvanse 60mg capsules.
5. **All ADHD service providers can now recommence initiating new and deferred patients on Elvanse® and Elvanse® Adult capsules and should consider utilising the 30mg, 50mg & 70mg titration schedule, where possible.**
6. Unlicensed supplies of lisdexamfetamine capsules can be sourced, lead times vary.
7. Generic dexamfetamine 5mg tablets and Amfexa (dexamfetamine) 5mg, 10mg, and 20mg tablets remain available but are unable meet large increases in demand.
8. This guidance supersedes MSAN(2024)06 issued on 6 March 2024.

### Advice and Actions

9. Where patients are affected by an intermittent supply disruption of Elvanse® capsules, primary care teams should:

    - check the SPS page on 'Prescribing available medicines to treat ADHD' for up-to-date information on availability of Elvanse® capsules and anticipated resupply dates before issuing a prescription;
    - consider prescribing unlicensed products only where licensed alternatives are not appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see supporting information below); and
    - if the above options are not considered appropriate, advice should be sought from specialists on management options.

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

ADHD service providers and specialists should:

- recommence initiating new and deferred patients on Elvanse® capsules, utilising a 30mg, 50mg & 70mg titration schedule, where possible;
- use their clinical judgment when initiating patients who may require titration at 10mg increments;
- take into account that Elvanse® 40mg, Elvanse Adult® 40mg and Elvanse® 60mg doses may be unavailable at times, which will limit titration options;
- offer advice to primary care teams seeking advice/opinion on the management of individual patients. This includes those known to be at a higher risk of adverse impact of these shortages.
- For example, those with co-morbidity autism, mental health or substance misuse ; and
- consider prescribing unlicensed products only where licensed alternatives are not appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see additional information below).

**Additional Information**

**Lisdexamfetamine**

10. A central nervous system stimulant licensed for treatment of attention deficit/hyperactivity disorder (ADHD) in children aged 6 years and over when response to previous methylphenidate treatment is considered clinically inadequate, and in adults with pre-existing symptoms of ADHD in childhood. It is a prodrug hydrolysed to dexamfetamine. The licensed dose ranges from 20mg to maximum of 70 mg once daily.
11. 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.

**Titrations**

12. Dose titration is usually led by the specialist.
13. For 6 – 17 year-olds: the starting dose is 30 mg taken once daily in the morning.
14. A lower starting dose of 20mg daily may be given to some patients based on clinical judgement.
15. The dose may be increased by 10 or 20 mg increments, at approximately weekly intervals. Lisdexamfetamine should be administered orally at the lowest effective dosage. The maximum recommended dose is 70 mg/day.
16. For adults: the starting dose is 30 mg taken once daily in the morning. The dose may be increased by 20 mg increments at approximately weekly intervals. The maximum recommended dose is 70 mg/day.

**Further guidance**

17. NICE guidelines recommend having regular planned treatment breaks from ADHD medications. Specialists should consider the appropriateness of treatment breaks with patients as per NICE guidance (NG87).

18. Prescribing teams should routinely check the Medicines Supply Tool on the Specialist Pharmacy Service (SPS) website for up-to-date information on resupply dates for Elvanse® presentations.

Links to further information

- SmPC: Elvanse hard capsules
- NICE guideline [NG87]: Attention deficit hyperactivity disorder
- SPS: Supporting system response to the ADHD medicine shortage
- SPS: Prescribing available medicines to treat ADHD

Guidance on ordering and prescribing unlicensed imports

19. The following specialist importers have confirmed they can source unlicensed Elvanse® capsules (please note there may be other companies that can also source supplies):

- Alium Medical (6-8 weeks lead time)
- Durbin (approx. 4 weeks lead time)
- Orifarm (4-6 weeks lead time)
- Target Healthcare (approx. next working day)

20. The following Specials manufacturers have confirmed they can supply unlicensed lisdexamfetamine capsules (please note there may be other companies that can also source supplies):

- Target Healthcare (1-2 days lead time)

21. 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.
22. 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**

23. 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.

24. 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**

25. 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).