Business Services Organisation

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Medicine Supply Notification: Lisdexamfetamine (Elvanse®) capsules

Tier 3 – high impact
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Medicines Supply Tool – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Summary

- There will be intermittent supply of all strengths of lisdexamfetamine (Elvanse®) capsules until April 2024.
- Supplies of various strengths of Elvanse® will be available at different times throughout this period.
- ADHD service providers should continue to defer initiating patients on Elvanse capsules as initiating new patients will prolong the current supply disruptions.
- Generic dexamfetamine 5mg tablets and Amfexa® (dexamfetamine) 5mg, 10mg, and 20mg tablets remain available but are unable meet large increases in demand.
- Unlicensed supplies of lisdexamfetamine capsules can be sourced, lead times vary.
- Supply disruptions affecting atomoxetine and guanfacine presentations have been resolved.

Actions Required

Where patients are affected by an intermittent supply disruption of Elvanse® capsules, primary care and community pharmacy teams should:

- work collaboratively to understand local stock availability of alternative strengths and issue a prescription to make up the required dose if possible;
- check the SPS 'Prescribing available medicines to treat ADHD' page for up-to-date information on availability of Elvanse® capsules and anticipated resupply dates;
- ensure lisdexamfetamine is prescribed on a separate prescription HS21.
- 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.

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ADHD service providers and specialists should:

- continue to defer initiating new patients on Elvanse® capsules; There are intermittent supply problems until Q2 2024. Initiating new patients will prolong this problem.
  offer rapid response to primary care teams seeking urgent advice/opinion for the management of patients. This includes those known to be at a higher risk of adverse impact because of these shortages. For example, those with complex presentations including co-morbid autism, mental health or substance misuse needs; and
- be aware dexamfetamine tablets remain available, and if switching patients to this treatment, ensure that they are not intolerant to any of the excipients and are counselled on the appropriate dose (see Supporting Information below).

Supporting information

Lisdexamfetamine

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 also 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.

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.

Dexamfetamine

Licensed for treatment of ADHD in children and adolescents aged 6 to 17 years when response to previous methylphenidate treatment is considered clinically inadequate. The licensed dose range is 5 mg once or twice daily up to usual maximum daily dose of 20mg (doses of 40mg may be used in rare cases).

NICE guidance recommends dexamfetamine as an option for patients whose ADHD symptoms are responding to lisdexamfetamine but who cannot tolerate the longer effect profile (off-label use).

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Further guidance

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).

Prescribing teams should routinely check the Medicines Supply Tool for up-to-date information on resupply dates for Elvanse® presentations.

Links to further information

- Elvanse hard capsules SmPC
- Dexamfetamine tablets SmPC
- NICE guideline for attention deficit hyperactivity disorder
- Supporting system response to the ADHD medicine shortage – SPS
- Prescribing available medicines to treat ADHD - SPS

Guidance on ordering and prescribing unlicensed imports

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. 4 weeks lead time)

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)

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust 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),