



Medicine Supply Notification

MSN/2024/051

Lisdexamfetamine (Elvanse®) capsules

Tier 3 – high impact*
Date of issue: 08/05/2024
Link: Medicines Supply Tool

Summary

- 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.
- There will however be intermittent supply issues with Elvanse[®] 40mg, Elvanse[®] Adult 40mg and Elvanse[®] 60mg capsules until August 2024.
- Elvanse® 20mg capsules remain available, but, cannot support an increase in demand during shortages of Elvanse® 40mg, Elvanse® Adult 40mg and Elvanse® 60mg capsules.
- Elvanse® 30mg capsules remain available and can support an increase in demand during the shortage of Elvanse 60mg capsules.
- All ADHD service providers can recommence initiating new and deferred patients on Elvanse[®] and Elvanse[®] Adult capsules and should consider utilising the <u>30mg, 50mg & 70mg titration</u> <u>schedule</u>, where possible.
- Unlicensed supplies of lisdexamfetamine capsules can be sourced, lead times vary.
- Generic dexamfetamine 5mg tablets and Amfexa (dexamfetamine) 5mg, 10mg, and 20mg tablets remain available but are unable meet large increases in demand.
- This guidance supersedes MSN/2024/019 issued in February 2024.

Actions Required

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;
- ensure lisdexamfetamine is prescribed on a separate prescription (FP10) or an electronic
 prescription. Do not send the electronic prescription to the nominated pharmacy unless it has been
 confirmed that the medicine is in stock or can be obtained by that pharmacy (see Supporting
 Information);
- 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.

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 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.

<u>NICE guidance</u> 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

Dose titration is usually led by the specialist.

For 6 – 17-year-olds: the starting dose is 30 mg taken once daily in the morning.

A lower starting dose of 20mg daily may be given to some patients based on clinical judgement.

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.

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

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

Prescribing teams should routinely check the <u>Medicines Supply Tool</u> for up-to-date information on resupply dates for Elvanse[®] presentations.

Prescribers and community pharmacies should refer to the <u>NHS Digital guidance</u> on how to use the Electronic Prescription Service (EPS) effectively to help patients when there are medicine supply issues.

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

NHS Digital: Medicine supply issues and use of the Electronic Prescription Service (EPS)

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. next working day)

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. 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:

- <u>The supply of unlicensed medicinal products</u>, 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),

When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the prescription that an unlicensed product is required. This can be done in one of the following two ways:

- Electronic prescriptions if the required unlicensed product is shown on electronic prescribing systems, GPs should select:
 - Vyvanse (imported)
 - Elvanse (imported)
- Paper prescriptions where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: "**special order**".

Enquiries

If you have any queries, please contact DHSCmedicinesupplyteam@dhsc.gov.uk.