Department of Health & Social Care

NHS England

Medicine Supply Notification

MSN/2024/086

Methylphenidate prolonged-release tablets

Tier 3 – high impact*
Date of issue: 22/08/2024
Link: Medicines Supply Tool

Summary

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

Actions Required

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®, 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.

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

- 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 Supporting Information); and to report any changes in symptoms or side effects after switching;

*Classification of Tiers can be found at the following link:
https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/

- 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 (FP10) or an electronic prescription which should not be sent to a nominated pharmacy unless the medicine is confirmed to be in stock at that pharmacy (see Supporting 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

Supporting information

Clinical Information

Methylphenidate

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.

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.

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

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.

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

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

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.

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

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

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)

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:

- 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),

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:

- Methylphenidate (18mg) prolonged-release tablets (imported)
- Methylphenidate (27mg) prolonged-release tablets (imported)
- Methylphenidate (36mg) prolonged-release tablets (imported)
- Methylphenidate (54mg) prolonged-release tablets (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.