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HSS(MD) 48/2023

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FOR ACTION

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GP Medical Advisers, SPPG
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Dear Colleague

NATIONAL PATIENT SAFETY ALERT – SHORTAGE OF METHYLPHENIDATE PROLONGED-RELEASE CAPSULES AND TABLETS, LISDEXAMFETAMINE CAPSULES, AND GUANFACINE PROLONGED-RELEASE TABLETS

Actions for healthcare professionals involved in prescribing or dispensing of methylphenidate prolonged-release capsules and tablets, lisdexamfetamine capsules, and guanfacine prolonged-release tablets.

Prescribers should:

1. not initiate new patients on products affected by this shortage until the supply issues resolve.

Healthcare professionals in primary care (and secondary care if appropriate) should:

2. identify all patients currently prescribed these products, and
3. make early contact with patients to establish how much supply they have remaining.

Where patients have insufficient supplies to last until the re-supply date (further information on product availability and anticipated resupply dates can be found on Specialist Pharmacy Service (SPS) Prescribing available medicine to treat ADHD page), contact:

4. community pharmacies, hospital pharmacy departments, or other dispensing pharmacy services, to establish availability of supply; and
5. patient's specialist team for advice on management options if the product cannot be sourced.

Specialist teams should:

6. support primary care teams seeking advice for patients currently prescribed the affected products,
7. provide individualised management plans, where required; and
8. recommend alternatives in line with NICE guidance, where appropriate.

Summary of identified safety issue

There are supply disruptions affecting various strengths of the following medications which are licensed for the treatment of attention deficit hyperactivity disorder (ADHD):

- **Methylphenidate:**
  - Equasym XL® 10, 20 and 30 mg capsules
  - Xaggitin XL® 18 and 36 mg prolonged-release tablets
  - Concerta XL® 54 mg prolonged-release tablets
  - Xenidate XL® 27 mg prolonged-release tablets

- **Lisdexamfetamine:**
  - Elvanse® 20, 30, 40, 50, 60 and 70 mg capsules
  - Elvanse® Adult 30, 50, and 70 mg capsules

- **Guanfacine**
  - Intuniv® 1, 2, 3 and 4 mg prolonged-release tablets

The supply disruption of these products is caused by a combination of manufacturing issues and an increased global demand.

Other ADHD products remain available but cannot meet excessive increases in demand.

At present, the supply disruptions are expected to resolve at various dates between October and December 2023.

Additional information

Supply information

Unlicensed imports of lisdexamfetamine (Vyvanse®) capsules and guanfacine (Intuniv®) prolonged-release tablets have been sourced. Lead times vary.

Limited parallel imports of methylphenidate (Equasym XL®) modified release capsules remain available but cannot support an uplift in demand.

A Medicine Supply Notification was issued in July 2023 for the shortage of atomoxetine capsules. The supply issue with atomoxetine is set to resolve in October 2023.

Clinical guidance

NICE recommends methylphenidate as the first line pharmacological treatment for children aged 5 years and over and young people with ADHD. Lisdexamfetamine is a second line option. Guanfacine is an option if they cannot tolerate methylphenidate or lisdexamfetamine or their symptoms have not responded to separate 6-week trials of lisdexamfetamine and methylphenidate. In adults with ADHD, lisdexamfetamine or methylphenidate are first-line pharmacological treatment options. These treatments must be initiated by healthcare professionals with training and expertise in diagnosing and managing ADHD, and patients should be periodically reviewed in line with NICE guidance.

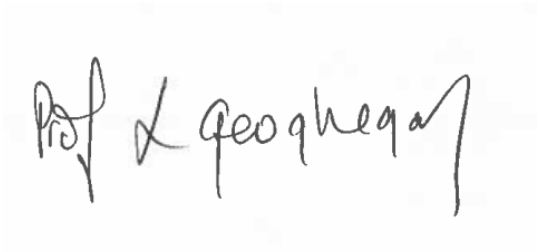
Changes to medication should be made with specialist input and discussed with patients and/ or their carers who should be advised to report any changes to their symptoms or development of side effects.

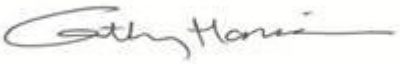
The MHRA advises caution if switching patients between different long-acting formulations of methylphenidate as different instructions for use and different release profiles may affect symptom management.

References

- NICE guideline [NG87]. Attention deficit hyperactivity disorder: diagnosis and management
- MHRA (2022). Methylphenidate long-acting (modified-release) preparations: caution if switching between products due to differences in formulations
- Specialist Pharmacy Service Prescribing available medicine to treat ADHD

Yours sincerely





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