Sheffield Place: Shortage of methylphenidate prolonged-release capsules and tablets, lisdexamfetamine capsules, and guanfacine prolonged-release tablets

Bottom Line: A National Patient Safety Alert (NPSA) has been sent out by CAS regarding supply disruptions affecting various strengths of medications which are licensed for the treatment of ADHD – see details in the link below: <u>NatPSA 2023 011 DHSC.pdf</u>

SPS has <u>a medicines supply tool</u> for the affected ADHD medicines (registration required). This includes anticipated re-supply dates and is regularly updated.

This link lists all the brands / strengths currently available - <u>Prescribing available medicines to treat</u> ADHD – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Anticipated re-supply dates provided by SPS supply tool:

Medicine	Anticipated re-supply date
Methylphenidate modified-release tablets <u>SPS supply tool</u> .	
Xenidate XL® 27mg tablets	31 October 2023
Xaggitin XL® 18mg tablets	1 February 2024
Xaggitin XL® 36mg tablets	1 February 2024
Methylphenidate modified-release capsules (Equasym XL®)	
SPS supply tool	
Equasym XL® 10mg capsules (Takeda UK Ltd)	30 October 2023
Equasym XL® 20mg capsules (Takeda UK Ltd)	30 October 2023
Equasym XL® 30mg capsules (Takeda UK Ltd)	27 November 2023
Lisdexamfetamine capsules (Elvanse®) SPS supply tool	
Elvanse® 50mg capsules (Takeda UK Ltd)	13 October 2023
Elvanse® 60mg capsules (Takeda UK Ltd)	20 October 2023
Elvanse® 70mg capsules (Takeda UK Ltd)	27 October 2023
Elvanse® Adult 30mg capsules (Takeda UK Ltd)	3 November 2023
Elvanse® Adult 50mg capsules (Takeda UK Ltd)	3 November 2023
Guanfacine modified-release tablets (Intuniv®) SPS supply tool	
Intuniv® 1mg modified-release tablets (Takeda UK Ltd) – OOS from 22 nd Oct	4 December 2023
Intuniv® 2mg modified-release tablets (Takeda UK Ltd) – OOS from 22 nd Oct	4 December 2023
Intuniv® 3mg modified-release tablets (Takeda UK Ltd) - OOS from 5th Nov	4 December 2023
Intuniv® 4mg modified-release tablets (Takeda UK Ltd)	20 November 2023

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. During this time no new patients should be started on medicines affected by this shortage.

Action required by primary care:

- All patients currently prescribed medicines affected by stock shortage should be identified (See <u>link</u> below for searches to support finding patients).
- Patients (and/or carers) should be contacted to establish how much supply they have remaining.
- Where patients have insufficient supplies to last until the re-supply date (as per above) liaise with community pharmacies regarding their current stock.
- If there are no supplies of existing treatment/strength see below for alternative options/advice from local specialists.
- For full and further information see the CAS alert (<u>NatPSA_2023_011_DHSC.pdf</u>).

Alternative preparations

Methylphenidate: For further information around alternatives see:

- SPS methylphenidate extended release characteristics and the relevant SPS supply tool.
 - PrescQIPP index (prescqipp.info).
- Practices will need to sign in to access these resources, registration is free.

In line with <u>MHRA advice</u> it is still important to prescribe extended-release methylphenidate by brand name to avoid confusion with other extended-release preparations which may have different release characteristics.

Delmosart PR®, Concerta XL®, Xaggitin XL®, Xenidate XL® (SPS supply tool)

- These brands of methylphenidate MR are considered bioequivalent and **patients can be switched between these brands depending on availability** (please liaise with local pharmacies as appropriate to enquire if alternative brand/s are available). Although this is a safe alternative, it should be seen as a temporary measure and patients should be switched back as soon as stocks return. These changes can be made without requiring review by or consultation with a specialist.
- Delmosart PR® is the Sheffield Formulary choice and information from the manufacturer advises that there should be sufficient availability.
- Note Delmosart PR® and Xaggitin XL® and are identical in tablet shape, colour, size, and markings; and almost identical to Concerta XL® apart from markings (<u>medicines.org</u>).
- Any change in brand should be clearly communicated and discussed with the patient (and/or guardian/carers) to explain the situation. Patient's (and/or guardian/carer) are advised to contact the GP surgery if there is any noticeable change in effect.

Equasym XL® (SPS supply tool Equasym XL)

- The biphasic release profile of Equasym XL® is different to any of the other brands; and there is no direct alternative. Note Different strengths of Equasym XL® may be available.
- Specialist importers of unlicensed medicines are unable to support this uplift, so we don't recommend considering this option.
- See <u>below</u> for specialist advice if the patient does not have sufficient supply to last until the resupply date.

Lisdexamfetamine (Elvanse®)

- There are no equivalent generic medicines available. Note Different strengths of lisdexamefetamine may be available.
- <u>SPS supply tool</u> shows this has specialist importers that can source unlicensed imports. See below for further information on <u>unlicensed medicines</u>.
- See <u>here</u> for specialist advice if the patient does not have sufficient supply to last until the resupply date.

Guanfacine (Intuniv®)

- There are no equivalent generic medicines available.
- <u>SPS supply tool</u> shows this has specialist importers that can source unlicensed imports. See below for further information on <u>unlicensed medicines</u>.
- See <u>here</u> for specialist advice if the patient does not have sufficient supply to last until the resupply date.
- Important: Guanfacine must not be stopped abruptly and needs re-titration if more than 2 consecutive doses are missed (see www.medicines.org.uk).

Local specialist advice

Sheffield Children's Hospital:

- All children being prescribed ADHD medication should be under a specialist.
- Parents of those under Ryegate and CAMHs will be contacted by SCFT to explain the situation (Text with link to a letter).
- SCFT are advising parents/carers to check with their local pharmacy first to see if their child's medication is available.
- If a child's medication is unavailable and/or supplies will run out prior to the expected resupply date:
 - The Neurodisability team (Ryegate) are advising the patient (or carer) to leave a message on their prescription line (0114 2717643).
 - A specialist will contact the family and discuss options. These will include taking a short-term medication break or prescribing an alternative brand or medication suitable for their child.
 - CAMHS Patients are being advised to contact care coordinators who can discuss options with patients and carers.

Adults (SHSC) / pts no longer under children services Local recommendations if no suitable alternatives (i.e. no bioequivalent alternative or strength)

Methylphenidate or lisdexamfetamine

Local specialist advice if patient does not have sufficient supply of methylphenidate or lisdexamfetamine to last until the re-supply date:

The table below is a summary of suggested considerations to be discussed and agreed with patients on a case-by-case basis.

Medication (number of adult pts on these strengths) anticipated resupply date	First line recommended action	Second line recommended action	Third line recommended action
Xenidate® 27mg - 31 st Oct Xaggitin® 18mg – Feb 24 Xaggitin® 36mg – Feb 24	Patients can be switched to an alternative brand with the same bioavailability - see <u>above</u> and information on <u>SPS</u> for details (log in required)	It is anticipated that all patients should be able to be prescribed an alternative bioequivalent brand	
Equasym® 10mg - 30 th Oct Equasym® 20mg - 30 th Oct Equasym® 30mg - 27 th Nov	Try sourcing from alternative pharmacy.	This is a short-term supply problem, a short treatment break/break of treatment at weekends (or days to suit individual) is local recommended advice. Those on 30mg - switch to 20mg when these are back in stock. If patients' symptoms are not controlled at this lower dose, add in 10mg to make up the 30mg	If a short term break in treatment is not feasible then discuss with initiating specialist service/SPA.

Elvanse® 50mg caps – 13 th Oct Elvanse® 60mg caps – 20 th Oct Elvanse® 70mg caps - 27th Oct Elvanse® Adult 30mg caps – 3rd Nov Elvanse® Adult 50mg caps – 3rd Nov Elvanse® Adult 50mg caps – 27th Oct	Try sourcing from alternative pharmacy.	dose. Switch back to the 30mg when these are back in stock. Those patients whose symptoms are controlled at the lower dose, maintain lower dose (shared decision with pt). This is a short-term supply problem, a short treatment break/break of treatment at weekends (or days to suit individual) is local recommended advice. There are currently supplies of the lower strengths (20mg, 30mg and 40mg) but it is anticipated these will be out of stock shortly. Prescribing a lower dose may be considered, where this is available – liaise with local pharmacy/ies.	If a short term break in treatment is not feasible then discuss with initiating specialist service/SPA
70mg caps - 27th		may be considered, where this is available – liaise with	

- This is a short-term supply problem, and if there is no suitable alternative a lower dose/ short break in treatment may be needed. Review by or consultation with a specialist is not required. It is common practice to consider treatment holidays / trial stop of medication / reduction of the dose if the overall balance of benefits and harms suggests this may be appropriate in order to assess continued need of ADHD medication. Stopping treatment in this way is not associated with significant withdrawal symptoms. Any break in treatment should be discussed with the patient (and/or carer) and effects of stopping reviewed.
- Where there is no bioequivalent alternative SHSC do not recommend changing patient's medication due to this short-term supply problem. See <u>contact details</u> for SPA if specialist advice required /referral needed/patient condition unstable.
- There is no specific guidance on whether the medicine needs re-titrating after a break in methylphenidate or lisdexamfetamine treatment.
 - Advice from local specialists may need to be sought. If a short period without the medicine (days) it can be re-started at their usual dose. If the patient has had an extended period without their medicine, they may need to re-titrate, depending on their original dose. Do not titrate up above previous dose prescribed.
- If during the break in treatment the patient has not had significant worsening of ADHD symptoms there is no need to restart the medication when the drug is back in stock (shared decision with patient). If there is uncertainty about the need to restart medication a specialist can be contacted for advice.

Guanfacine:

- All patients on guanfacine should be under shared care arrangements.
- Patients prescribed guanfacine who cannot get access to supplies should be referred to the appropriate specialist as **guanfacine should not be stopped abruptly**, specialist oversight is recommended.
- Due to the risk of rebound hypertension when stopping guanfacine treatment it should be titrated down ideally by 1mg every 3 to 7 days prior to stopping.
- The patients` blood pressure and heart rate should be monitored weekly during this period. Primary care are encouraged to work with specialist colleagues should patients need to be monitored in this way.
- It is recommended to ask the patient (and/or carer) to save at least 3 days of the lower dosage/s, if they have them, so they can titrate the dose down if this is needed. Depending on the current dose prescribed primary care should consider providing a prescription of lower strength tablets so that should guanfacine be unavailable the dose can be tapered down at a maximum rate of 1mg every 3 days.
- Patients will need to be titrated up slowly if there is a break in treatment for longer than 2 consecutive days. In such situations this should be over seen by the specialist.

Regarding unlicensed alternatives available from specialist importers:

- We are currently working to find out if community pharmacies can get the unlicensed medicine alternatives listed in the SPS supply tool.
- We expect that pharmacies will not have an account with these specialist importers; and setting one up can take time.

Signposting patients and/or carers to resources to help manage ADHD symptoms through non-pharmacological options:

Attention deficit hyperactivity disorder (ADHD) - Treatment - NHS (www.nhs.uk)

Contact details for primary care colleagues

- Ryegate Ask the families to ring the prescription line number.
- CAMHs Ask the family to contact their case worker.

Sheffield Health and Social care

Single Point of Access (SPA) Tel: (0114) 226 3636

Email - sct-ctr.spa-adult-mental-health@nhs.net

Pharmacy Department, Sheffield Health and Social Care NHS Foundation Trust el No. 0114 2718633

Psychiatry UK

Urgent-Update-Regarding-National-ADHD-Medication-Shortage_1.pdf (psychiatry-uk.com)

ADHD360

National Shortage Of Medication For ADHD | News | ADHD 360 (adhd-360.com)

References

- CAS alert <u>NatPSA 2023 011 DHSC.pdf</u>
- SPS prescribing available medicines to treat ADHD
- SPS <u>Medicines supply tool</u>
- Shared Care / Prescribing Guideline For The management of prescribing for Attention Deficit/Hyperactivity Disorder (ADHD). <u>https://www.intranet.sheffieldccg.nhs.uk/Downloads/Medicines%20Management/Shared%20Car</u> <u>e%20protocols/ADHD_SCP.pdf</u>
- PrescQIPP: PrescQIPP Prescribing in attention deficit hyperactivity disorder (ADHD
- Summary of product Characteristics: <u>https://www.medicines.org.uk/emc.</u>

Searches which are available to practices:

- 1) Methyphenidate brands on repeat-stock shortage-see NatPSA | Age <18 years
- 2) Methyphenidate brands on repeat-stock shortage-see NatPSA | Age 18 years and older
- 3) Elvanse or generic on repeat-stock shortage-see NatPSA | Age<18 years
- 4) Elvanse or generic on repeat-stock shortage-see NatPSA | Age 18 years and older
- 5) Intuniv or generic on repeat stock shortage see NatPSA | Age<18 years
- 6) Intuniv on repeat stock shortage see NatPSA | Age 18 years and older

Below is the location of where they can be found:

SystmOne:Reporting>Clinical Reporting>Sheffield Practices>Medicines Optimisation Team 2023 2024>NatPSA 2023 011 DHSC

EMIS Web: Population Reporting>BBS IT Services – Enterprise Search and Reports>Sheffield CCG Medicines Optimisation Team>NatPSA/2023/011/DHSC. (Practices will need to copy and paste these into a folder of their choice before they can run them)

Medicines Optimisation Team, Sheffield Place SY ICB in partnership with SC(NHS)FT and SHSC colleagues.