

## Children and Young People ADHD - Lisdexamfetamine Shared Care Protocol



Nottinghamshire Area Prescribing Committee

V1.0	Last reviewed: January 2024	Review date: January 2027
------	-----------------------------	---------------------------

# Lisdexamfetamine for patients within children and young people services

Adapted from local adult ADHD shared care protocol which is based on the national adult template published by NHS England .

Traffic light classification- AMBER 1

The content of this shared care protocol was correct as of January 2024. Please ensure that [summaries of product characteristics](#) (SPCs), [British national formulary](#) (BNF) or the [Medicines and Healthcare products Regulatory Agency](#) (MHRA) or [NICE](#) websites are reviewed for up-to-date information on any medicine.

# Children and Young People ADHD - Lisdexamfetamine Shared Care Protocol

V1.0	Last reviewed: January 2024	Review date: January 2027
------	-----------------------------	---------------------------

## Specialist responsibilities

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol ([section 2](#)) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see [section 11](#)), to enable them to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see [section 4](#)) and interactions (see [section 7](#)).
- Conduct required baseline investigations and initial monitoring (see [section 8](#)).
- Initiate and optimise treatment as outlined in [section 5](#). Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Prescribe in line with controlled drug prescription requirements ([section 6](#)).
- Once treatment is optimised, write to the patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include the specialist service contact information ([section 13](#)).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the required monitoring in [section 8](#) and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 9](#) remains appropriate. Trial discontinuations should be managed by the specialist.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

## Primary care responsibilities

- If shared care is not accepted, inform the specialist of the decision in writing within 14 days with reasons as to why shared care cannot be entered into.
- If accepted, prescribe ongoing treatment as detailed in the specialists request and as per [section 5](#) taking into account any potential drug interactions in [section 7](#).
- Prescribe in line with controlled drug prescription requirements ([section 6](#)).
- Adjust the dose of lisdexamfetamine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in [section 9](#). Communicate any abnormal results to the specialist.
- Assess for possible interactions with lisdexamfetamine when starting new medicines (see [section 7](#))
- Manage adverse effects as detailed in [section 10](#) and discuss with specialist team when required.
- Stop lisdexamfetamine and make an urgent referral for appropriate care if cerebral ischaemia, new or worsening seizures, or serotonin syndrome are suspected. See [section 10](#)
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.
- Ensure the patient is given the appropriate appointments for monitoring. If a patient fails to attend, contact the patient in a timely manner and arrange an alternative appointment.

## Patient and/or carer responsibilities

- Take lisdexamfetamine as prescribed and avoid abrupt withdrawal unless advised by primary care prescriber or specialist.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their GP. Seek immediate medical attention if they develop any symptoms as detailed in [section 11](#).
- Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of lisdexamfetamine with their pharmacist before purchasing any OTC medicines.

- Be aware that lisdexamfetamine can affect cognitive function and is subject to drug driving laws, therefore patients must ensure their ability to drive is not impaired before driving (see [section 11](#)).
- Avoid alcohol during treatment, as it may make some side effects worse. Avoid recreational drugs. Lisdexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store lisdexamfetamine safely and securely. It must not be shared with anyone else.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

## 1. Background

[Back to top](#)

Lisdexamfetamine dimesylate is metabolised following administration to dexamfetamine and therefore has the same sympathomimetic mechanism of action with central stimulant and anorectic activity. The mode of therapeutic action of amphetamine in ADHD is not fully established, however is thought to be due to its ability to block the reuptake of noradrenaline and dopamine into the presynaptic neuron and increase the release of these monoamines into the extra neuronal space. It is indicated as part of a comprehensive treatment programme for the treatment of attention deficit hyperactivity disorder (ADHD) when the response to a 6-week trial of methylphenidate treatment is considered clinically inadequate. Treatment with lisdexamfetamine should only be initiated by a specialist with expertise in ADHD following a comprehensive assessment and diagnosis. NICE recommend that GPs should continue prescribing and monitoring medication treatment under shared care arrangements. Use in combination with atomoxetine is felt to be clinically appropriate. NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs. (see [NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management](#)).

Whilst [NICE guidance](#) state that medication can be prescribed from the age of 5, this is unlicensed and done with caution in exceptional circumstances by specialists therefore children < 6 years old are excluded from this shared care protocol. Patients ≥ 18 years old are covered by a separate [shared care protocol](#).

Lisdexamfetamine is a schedule 2 controlled substance; all legal requirements for prescribing controlled drugs should be followed. See NICE Guidance [NG46 Controlled drugs: safe use and management](#).

Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) or Community Paediatrics team but is approaching their 18<sup>th</sup> birthday, it is expected that CAMHS or Community Paediatrics team will refer to the appropriate adult service if need for ongoing treatment is anticipated. See the Nottinghamshire Area Prescribing Committee shared care protocol and medication information leaflets for adult ADHD at:

<https://www.nottsapc.nhs.uk/shared-care/>.

Pharmacological treatment of ADHD may be needed for extended periods. When lisdexamfetamine is used for extended periods (over 12 months) its usefulness should be re-evaluated at least yearly by a healthcare professional with expertise in ADHD, and consideration given to trial periods off medication to assess the patient's functioning without pharmacotherapy.

## Indications

[Back to top](#)

Licensed indication: attention deficit hyperactivity disorder (ADHD) in children aged 6 years and over

Whilst [NICE guidance](#) state that medication can be prescribed from the age of 5, this is unlicensed and done with caution in exceptional circumstances by specialists therefore children < 6 years old are excluded from this shared care protocol. Patients ≥ 18 years old are covered by a separate [shared care protocol](#).

See [SPC](#) for full details of licensed indication.

## Locally agreed off-label use

[Back to top](#)

**Not applicable**

## Contraindications and cautions

[Back to top](#)

This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see [BNF](#) & [SPC](#) for comprehensive information.

### 4. Contraindications:

- Known hypersensitivity to the active substance, any of the excipients, or sympathomimetic amines.
- Glaucoma.
- Symptomatic cardiovascular disease.
- Moderate or severe hypertension.
- Advanced arteriosclerosis.
- Concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days of MAOI treatment.
- Hyperthyroidism or thyrotoxicosis.
- Agitated states.

### Cautions:

- History of substance or alcohol abuse.
- Cardiovascular disorders such as structural cardiac abnormalities, cardiomyopathy, arrhythmias, coronary artery disease, mild hypertension, recent myocardial infarction, or heart failure.
- Sudden death has been reported in children and adolescents taking CNS stimulants, including those with structural cardiac abnormalities or other serious heart problems. Not for use in children or adolescents with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities or other serious cardiac problems that may place them at increased vulnerability to the sympathomimetic effects of a stimulant medication. Family history of sudden cardiac or unexplained death, ventricular arrhythmia, tics or Tourette's syndrome.
- Underlying medical conditions or concomitant drugs which can increase the QT-interval or heart rate, or elevate blood pressure (e.g. cardiac disease, electrolyte disturbance).
- History of seizure disorders (discontinue if seizures occur). Stimulants may lower the convulsive threshold in patients with prior history of seizure. In the presence of new onset or worsening seizures the medication should be discontinued
- Susceptibility to angle-closure glaucoma.

- Psychiatric and neuropsychiatric symptoms or disorders, including manic or psychotic symptoms, aggressive or hostile behaviour), tics, Tourette's syndrome, anxiety, or bipolar disorder. Stimulants may exacerbate symptoms of behaviour disturbance and thought disorder in patients with pre-existing psychotic disorders. Depressive symptoms; patients should be screened for risk of bipolar disorder, including psychiatric and family histories.
- Treatment emergent psychotic or manic symptoms can be caused by stimulants at usual doses. If these occur, consider the potential role of the stimulant, and discontinuation of treatment may be appropriate.
- Stimulants have been associated with a slowing of weight gain and a reduction in attained height. Monitor growth during treatment with stimulants.
- Severe renal impairment; GFR 15-30mL/min/1.73m<sup>2</sup> or CrCl less than 30mL/min. Dose reduction is required, the maximum dose should not exceed 50 mg/day. see [section 5](#).
- Hepatic insufficiency (due to lack of data).
- Pregnancy or breast-feeding (see [section 12](#)).
- Potential for abuse, misuse, or diversion.

## Initiation and ongoing dose regimen

[Back to top](#)

5. • Transfer of monitoring and prescribing to primary care is normally after the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician
- Termination of treatment will be the responsibility of the specialist unless in the case of managing adverse effects as detailed in [section 10](#)

### **Initial stabilisation:**

- 30 mg taken once daily in the morning, increased in increments of 10mg or 20 mg at intervals no shorter than 1 week. Lower starting doses may be used if clinically appropriate (off-label use) with 20mg once daily in the morning

**The loading period must be prescribed by the initiating specialist.**

### **Maintenance dose (following initial stabilisation):**

Maximum 70 mg per day. Higher doses have not been studied.

**Lisdexamfetamine must be prescribed by the initiating specialist during initiation and dose stabilisation. The initial maintenance dose must be prescribed by the initiating specialist. Specialist will inform GP on any subsequent doses . GPs should not alter any**

doses without discussing with specialist unless stopping due to side effects. See [section 10](#).

Where a patient has been switched between medications (i.e. lisdexamfetamine to dexamfetamine) further monitoring may be required, as per specialist instruction.

### Duration of treatment

Following an adequate treatment response, medication treatment for ADHD should be continued for as long as it remains clinically effective. This should be reviewed at least annually by the specialist.

### Conditions requiring dose adjustment:

In severe renal impairment (GFR 15-30mL/min/1.73m<sup>2</sup> or CrCl less than 30mL/min), the recommended maximum dose is 50 mg per day.

Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. This should be undertaken and supervised by the specialist who will advise the patient and GP of the outcome.

## 6. Pharmaceutical aspects

[Back to top](#)

Route of administration:	Oral
Formulation:	Lisdexamfetamine dimesylate 20mg, 30mg, 40mg, 50mg, 60mg and 70mg hard capsules (Elvanse®) – It is advised to prescribe Lisdexamfetamine by brand due to differences in licensing between Elvanse® Adult and Elvanse®.
Administration details:	The dose may be taken with or without food  Lisdexamfetamine capsules may be swallowed whole, or the capsule opened and the entire contents emptied and mixed with a soft food such as yogurt or in a glass of water or orange juice. See <a href="#">SPC</a> for further information



	<p>If a dose is missed then the next scheduled dose should be taken as usual; <u>a double dose should not be taken to make up for a missed dose</u>. Afternoon doses should be avoided because of the potential for insomnia</p>
Other important information:	<p>Lisdexamfetamine is a schedule 2 controlled drug and is subject to <a href="#">legal prescription requirements</a>. It has the potential for misuse and diversion.</p> <p>Patients should be advised to avoid alcohol which may exacerbate the central nervous system (CNS) side-effects of lisdexamfetamine</p> <p>Amfetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amfetamines may interfere with urinary steroid determinations</p>

## Significant medicine interactions

[Back to top](#)

7. The following list is not exhaustive. Please see [BNF](#) or [SPC](#) for comprehensive information and recommended management.

### The following medicines must not be prescribed without consultation with the specialist:

- **Mono-amine oxidase inhibitors (MAOIs) and other sympathomimetics** (e.g. rasagiline, selegiline, safinamid, isocarboxazid, moclobemide, phenelzine and tranylcypromine - lisdexamfetamine should not be used in combination with MAOIs or within 2 weeks of stopping a MAOI due to risk of hypertensive crisis) – additive hypertensive effect

### Other clinically significant interactions

- **Selective serotonin reuptake inhibitors (SSRIs) (e.g. fluoxetine, paroxetine):** may increase exposure to lisdexamfetamine, risk of serotonin syndrome
- **Serotonergic drugs, bupropion, tapentadol, tramadol:** Risk of serotonin syndrome
- **Tricyclic antidepressants (TCAs) and nabilone:** may increase risk of cardiovascular adverse events.
- **Ascorbic acid and other agents and conditions (thiazide diuretics, diets high in animal protein, diabetes, respiratory acidosis)** that acidify urine increase urinary excretion and decrease the half-life of amfetamine.
- **Sodium bicarbonate and other agents and conditions (diets high in fruits and vegetables, urinary tract infections and vomiting)** that alkalinise urine decrease urinary excretion and extend the half-life of lisdexamfetamine.

- **Antihypertensives, including guanethidine:** effects may be reduced by lisdexamfetamine
- **Lithium, phenothiazines, haloperidol:** may reduce the effects of lisdexamfetamine
- **Opioids** (including tapentadol and tramadol): analgesic effects may be increased by lisdexamfetamine
- **Alcohol:** Limited data is available, therefore caution is advised as alcohol may exacerbate the CNS side effects of lisdexamfetamine
- **Apraclonidine:** effects decreased by lisdexamfetamine.
- **Ritonavir, tipranavir:** may increase exposure to lisdexamfetamine
- **Safinamide:** predicted to increase the risk of severe hypertension when given with lisdexamfetamine
- **Atomoxetine:** increased risk of adverse effects
- Amfetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening.
- Guanfacine plasma concentrations are increased by lisdexamfetamine; this is not expected to be clinically meaningful.
- Venlafaxine. Conversion to the active metabolite o-desmethylvenlafaxine may be reduced by lisdexamfetamine; this is not expected to be clinically meaningful

## 8. **Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist**

[Back to top](#)

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

### **Baseline investigations:**

- A full assessment, as recommended by [NICE guidance for ADHD. This should include](#) medical history and cardiovascular assessment, taking into account conditions that may be contraindications, risk of pregnancy (where applicable), and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required.
- Pre-treatment assessment to be performed will include diagnostic interview, behavioural rating scales (e.g., SDQ, Conners', CAARS self and observer report) and descriptive reports from parents and teachers.
- A risk assessment for substance misuse and drug diversion
- Height, weight (measured and recorded against normal range for age, height and sex), appetite and body mass index (BMI)

- Baseline blood pressure (BP) and heart rate (measured with appropriately sized cuff and compared with normal range for age)
- 
- A cardiovascular assessment.  
An electrocardiogram (ECG) is not needed before starting, lisdexamfetamine unless the person has any features [below](#) or a co- existing condition being treated with a medicine that may pose an increased cardiac risk.
- Arrange for electrocardiogram (ECG) /echocardiogram /refer for cardiology opinion before starting medication, only if the patient has any of the following:
  - History of congenital heart disease or previous cardiac surgery
  - History of sudden death in a first-degree relative under 40 years suggesting a cardiac disease
  - Shortness of breath on exertion compared with peers
  - Fainting on exertion or in response to fright or noise
  - Palpitations that are rapid, regular and start and stop suddenly (fleeting occasional bumps are usually ectopic and do not need investigation)
  - Chest pain suggestive of cardiac origin
  - Signs of heart failure or heart murmur
  - Current treatment with a medicine that may increase cardiac risk
  - Blood pressure that is classified as hypertensive.

Refer to a paediatric hypertension specialist before starting a medication for ADHD if blood pressure is consistently above the 95<sup>th</sup> centile for age and height for children and young people. Information on blood pressure and heart rate monitoring in children (including centile reference tables) is available on the [Nottinghamshire Area Prescribing Committee website](#).

#### **Initial monitoring:**

- Before every change of dose: assess heart rate, blood pressure, and weight.
- After every change of dose: assess heart rate and blood pressure, and any new or worsening psychiatric symptoms. The specialist should determine the appropriate timing for this monitoring as no standard is given in literature..
- Monitor for aggressive behaviour or hostility
- Assessment of symptom improvement. Discontinue if no improvement is observed after one month.

**Ongoing monitoring (ADHD):** Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document the reasons why.

Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone or electronic records such as System1 where available.

**If the child / young person fails to attend for physical monitoring, despite attempts to re-appoint, do not issue any further prescriptions, contact the patient/carer and inform the specialist. The patient should be informed of this policy when treatment begins.**

## Ongoing monitoring requirements to be undertaken by primary care

[Back to top](#)

See [section 10](#) for further guidance on management of adverse effects/responding to monitoring results.

Monitoring and advice	Frequency
<ul style="list-style-type: none"> <li>Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms</li> </ul>	<p>Every 6 months, before and after any change of dose recommended by specialist team**.</p> <p>Compare with previous measurements and with the normal range for age.</p> <p>Information on blood pressure and heart rate monitoring in children (including centile reference tables) is available on the <a href="#">Nottinghamshire Area Prescribing Committee website</a>.</p> <p>See <a href="#">section 10</a> for further guidance on management</p>

<ul style="list-style-type: none"> <li>• Assessment for new or worsening psychiatric and neurological signs or symptoms (e.g. tics, anxiety, symptoms of bipolar disorder)</li> <li>• Explore whether patient is experiencing any</li> <li>• difficulties with sleep</li> </ul>	<p>Every 6 months, before and after any change of dose recommended by specialist team**.</p>
<ul style="list-style-type: none"> <li>• Weight and appetite</li> </ul>	<p>Following initiation:</p> <ul style="list-style-type: none"> <li>• Every 3 months in children 10 years and under.</li> <li>• Measure weight at 3 and 6 months after starting treatment in children over 10 years and young people and every 6 months thereafter, or more often if concern arise.</li> </ul> <p>Plot on a growth chart (link: <a href="http://www.rcpch.ac.uk/growthcharts">http://www.rcpch.ac.uk/growthcharts</a>).</p> <p>If weight loss or reduced weight gain this should be discussed with the specialist.</p>
<ul style="list-style-type: none"> <li>• Height</li> </ul>	<p>Six monthly.</p> <p>Plot on a growth chart.</p> <p>If growth is affected significantly this should be discussed with the specialist.</p>
<ul style="list-style-type: none"> <li>• Medication related side-effects*</li> </ul>	<p>At each visit</p>
<ul style="list-style-type: none"> <li>• ECG, LFTs, FBC</li> </ul>	<p>Not recommended unless there is a clinical indication.</p>
<ul style="list-style-type: none"> <li>• Assessment of adherence, and for any indication of lisdexamfetamine abuse, misuse, or diversion</li> </ul>	<p>As required, based on the patient's needs and individual circumstances</p>
<ul style="list-style-type: none"> <li>• Review to ensure patient has been offered and attended an annual review with a</li> </ul>	<p>Annually</p>

healthcare professional with expertise in ADHD	
--	--

\*Consider using standard symptom and side effect rating scales during treatment as an adjunct to clinical assessment.

\*\* The specialist should determine the appropriate timing for this monitoring as no standard is given in literature

**If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.**

## Adverse effects and other management

[Back to top](#)

**Any serious adverse reactions should be reported to the MHRA via the Yellow Card (scheme). Visit [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)**

For information on incidence of ADRs see relevant summaries of product characteristics

[European guidelines on managing adverse effects of medication for ADHD](#) were published in 2011. These provide additional guidance for clinicians

**IF YOU ARE IN ANY DOUBT ABOUT ANY POTENTIAL ADVERSE REACTION, PLEASE CONTACT THE SPECIALIST TEAM.**

**If the child in front of you is acutely unwell, please contact the oncall general paediatric team**

Result	Action for primary care
--------	-------------------------

**As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.**

Sustained resting tachycardia, arrhythmia/palpitations, clinically significant increase in systolic blood pressure is persistently above 95 th centile for age and height.	Withhold or reduce dose and review for acute additional symptoms. If present refer to general paediatric team. If no additional symptoms inform specialist and refer to a paediatric hypertension specialist as soon as possible
--	--

	Information on blood pressure and heart rate monitoring in children (including centile reference tables) is available on the <a href="#">Nottinghamshire Area Prescribing Committee website</a> .
Symptoms of cerebral ischaemia, e.g. severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory	Discontinue lisdexamfetamine, refer urgently for neurological assessment
<p><b>Haematological disorders</b></p> <p>Including leukopenia, thrombocytopenia, anaemia related symptoms (e.g. paleness, lethargy) or other alterations</p> <p>Abnormal bruising / bleeding / severe sore throat / skin lesions or severe infection</p> <p>NB: no haematological monitoring is recommended. Haematological disorders would be a chance finding/due to patient reporting adverse drug reactions.</p>	Seek immediate medical attention, Not known to be related to lisdexamfetamine
New or worsening seizures	Discontinue lisdexamfetamine and discuss with specialist team or oncall team immediately
Anorexia or weight loss, weight or BMI outside healthy range	<p>Exclude other reasons for weight loss. Exclude other reasons for weight loss. Give advice as per <a href="#">NICE NG87</a>:</p> <ul style="list-style-type: none"> <li>• take medication with or after food, not before</li> <li>• additional meals or snacks early in the morning or late in the evening when stimulant effects have worn off</li> <li>• obtaining dietary advice</li> </ul>

	<ul style="list-style-type: none"> <li>• consuming high-calorie foods of good nutritional value</li> </ul> <p>Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be required.</p>
Insomnia, sleep disturbance/nightmares, sedation, sexual dysfunction	Review timing of doses and continue treatment unless severe, Give advice on sleep hygiene. Discuss with specialist if required
Nausea, diarrhoea, abdominal cramps, constipation, dry mouth, headache, dizziness, enuresis, increased daytime urination, tics	Continue treatment unless severe. Some symptoms may be alleviated by concomitant food intake. Discuss with specialist if required
New or worsening psychiatric or neuropsychiatric symptoms, e.g. , e.g. psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, bipolar disorder, depression, paranoia, anxiety and agitation	Discuss with specialist. Stop treatment and consider referral to acute mental health team if suicidal thoughts, mania, or psychosis are present
Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea	Discontinue lisdexamfetamine and discuss with specialist team or oncall team immediately c
Suspicion of abuse, misuse, or diversion	Discuss with specialist team
Failure to attend for physical monitoring checks	Do not issue further prescriptions, discuss as soon as possible with specialist.



## Advice to patients and carers

[Back to top](#)

The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

### **The patient/carer should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:**

- Any mood changes, such as depression, paranoia, anxiety or agitation, psychosis, mania and suicidal ideation
- Palpitations, chest pain or syncope
- Cerebrovascular symptoms, such as severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language, or memory
- Abdominal pain, malaise, jaundice or darkening of urine
- Skin rashes, or bruising easily
- Any visual changes such as difficulty with accommodation or blurring of vision
- If they suspect they may be pregnant, or are planning a pregnancy. Patients of childbearing potential should use appropriate contraception, and take a pregnancy test if they think there is a possibility they could be pregnant.

### **The patient/carer should be advised:**

- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. It may not be safe to continue prescribing without regular review, and patients should be aware that their medicines could be stopped if they do not attend appointments.
- Lisdexamfetamine can affect impair cognitive function and is subject to drug driving laws, therefore patients must ensure their ability to drive is not impaired before driving. For information on 2015 legislation regarding driving whilst taking certain controlled drugs, including amfetamines, see [drugs and driving: the law](#). People who drive must inform the DVLA if their ADHD, narcolepsy or medicines affect their ability to drive safely. See <https://www.gov.uk/adhd-and-driving> or <https://www.gov.uk/narcolepsy-and-driving>.
- Avoid alcohol while taking lisdexamfetamine, as it may make some side effects worse. Avoid recreational drugs. Due to the risks of severe depression, and fatigue, abrupt withdrawal after a prolonged period of intake of high doses of lisdexamfetamine should be avoided.

Patients wishing to reduce their dose or stop lisdexamfetamine treatment should discuss with their specialist before doing so.

- Lisdexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store lisdexamfetamine safely and securely. It must not be shared with anyone else. There are restrictions on travelling with controlled drugs: see <https://www.gov.uk/guidance/controlled-drugs-personal-licences>.

#### **Patient information:**

- Royal College of Psychiatrists – ADHD in adults. <https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults>
- NHS – Attention deficit hyperactivity disorder. <https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/>
- Patient information leaflets are also available from: [Choice and Medication](#)

## **Pregnancy, paternal exposure and breast feeding**

[Back to top](#)

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

#### **Pregnancy:**

The active metabolite of lisdexamfetamine, dexamfetamine, is thought to cross the placenta. The limited data available shows an increased risk of premature birth and preeclampsia. Infants may also develop withdrawal symptoms such as dysphoria, hyperexcitability and pronounced exhaustion.

If a patient becomes pregnant or is planning a pregnancy during treatment they should discuss treatment options with their specialist. The specialist will reassume prescribing responsibility, ending the shared care agreement. Lisdexamfetamine should only be used during pregnancy if the potential benefit outweighs the risks.

Healthcare professional information available from:

[USE OF THERAPEUTIC AMFETAMINES IN PREGNANCY – UKTIS](#)

Patient information available from [bumps - best use of medicine in pregnancy \(medicinesinpregnancy.org\)](https://www.bumps-bestuseofmedicineinpregnancy.org)

#### **Breastfeeding:**

There is no published evidence for safety of lisdexamfetamine in breastfeeding. The manufacturers recommend against use, and the UK Drugs in Lactation Service recommend caution (see link below). Lisdexamfetamine metabolites, including dexamfetamine, are excreted in human milk, therefore a risk to infants cannot be excluded. An individual risk assessment

must be made, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Healthcare professional information available from: <https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/>

**Paternal exposure:**

No evidence regarding adverse outcomes following paternal exposure was identified.

## Specialist contact information

[Back to top](#)

13.

Child and Adolescent Mental Health Services (CAMHS 0115 8440500

Community Paediatrics ((Queens Medical Centre NUH) 0115 840 4848.

Community Paediatrics - Mansfield, Newark, Ollerton, Ashfield excluding Hucknall) at Sherwood Forest Hospitals NHS Foundation Trust

01623-622515

Nottinghamshire Healthcare NHS Foundation Trust Pharmacy advice line (for healthcare professionals): 0300 303 5808 and email: [MI@nottshc.nhs.uk](mailto:MI@nottshc.nhs.uk)

Nottingham University Hospital QMC Pharmacy Medicines Information 0115 924 9924  
Extension 84185/81200

Sherwood Forest Hospitals NHS Foundation Trust Pharmacy Medicine Information 01623-672213

Wells Road Centre Pharmacy Medicine information 01159-555357

### **Out of Hours**

Contact on-call CAMHS Psychiatrist via Nottinghamshire Healthcare NHS Foundation Trust 0118440500

Oncall Paediatricians

Nottinghamshire South (Nottingham University Hospital QMC) 0115-8831181

Nottinghamshire North (Sherwood Forest Hospitals NHS Foundation Trust) 01623-622515.

Other local NHS specialists may request shared care including local mental health teams and intellectual disability teams. The contact details for these teams will be detailed on the shared care request letter.

## Additional information

[Back to top](#)

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed of any changes to the patient's GP or their contact details.

All involved healthcare professionals should ensure a prompt transfer of care that includes effective information sharing and continued access to the medicines by the patient during the transition.

## References

[Back to top](#)

15. NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via <https://www.nice.org.uk/guidance/ng87/> on 07/02/2023
- eBNFc. Lisdexamfetamine, last updated 14 December 2022. Accessed via <https://bnfc.nice.org.uk/> on 07/02/2023
- Lisdexamfetamine dimesylate 20 mg hard capsules (Elvanse®). Date of revision of the text: 11/01/21. Accessed via <https://www.medicines.org.uk/emc/product/2979/smpc> on 13/05/21
- Lisdexamfetamine dimesylate 30 mg hard capsules (Elvanse® Adult). Date of revision of the text: 01/11/22. Accessed via <https://www.medicines.org.uk/emc/product/6828/smpc> on 07/02/23
- The Renal Association. CKD Stages. Accessed via <https://renal.org/health-professionals/information-resources/uk-eckd-guide/ckd-stages> on 07/02/23
- NICE. NG46: Controlled drugs: safe use and management. April 2016. Accessed via <https://www.nice.org.uk/guidance/ng46/> on 07/02/2023
- Gov.uk: Drugs and driving: the law Gov.uk. Drugs and driving: the law. Accessed via <https://www.gov.uk/drug-driving-law> on 07/02/23
- Specialist Pharmacy Service. Safety in Lactation: Drugs for ADHD. Last updated October 2020. Accessed via <https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/> on 07/02/2023
- NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: last revised November 2022. Accessed via <https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/amfetamines/> on 07/02/23

## Other relevant national guidance

[Back to top](#)

- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from <https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/>
- 16. • NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from <https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/>
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care>
- NICE NG197: Shared decision making. Last updated June 2021. <https://www.nice.org.uk/guidance/ng197/>.

## Local arrangements for referral

[Back to top](#)

17 Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

- Prescribing and monitoring responsibility will only be transferred when the patient's condition and medication are stable.
- The specialist will request shared care with the GP in writing.
- If the GP doesn't agree to shared care, they should inform the specialist of their decision in writing within 14 days.
- In cases where shared care arrangements are not in place or where problems have arisen within the agreement and patient care may be affected, the responsibility for the patients' management including prescribing reverts back to the specialist.
- Should the patient's condition change, the GP should contact the relevant specialist using the details provided with the shared care request letter.

## 18. Version Control - Lisdexamfetamine shared care protocol

Version	Author(s)	Date	Changes
1.0	Vimbayi Mushayi, Specialist Interface Medicine Optimisation Pharmacist. Nottingham and Nottinghamshire ICB	January 2024	<p>from local and National adult template published by NHS England</p> <p>The information is cross-referenced between the national template and the local shared care guidelines.</p> <p>Additional information included to reflect the locally agreed shared care protocol</p> <p>Consultations:</p> <p>Dr Amy Taylor Consultant in Paediatric Neurodisability/Community Paediatrics Nottingham Children's Hospital</p> <p>Dr Esther Corker Consultant Community Paediatrician Head of Service and Neurodevelopmental Lead Kings Mill Hospital</p> <p>Susan Doherty Lead ADHD Specialist Nurse Community Paediatrics</p> <p>Joe Kilgariff Trainee Advanced Clinical practitioner (ACP)</p> <p>Woodrow Blake Lead Pharmacist for Intellectual Disabilities &amp; Neurodevelopmental Disorders</p>

