

Lisdexamfetamine and Dexamfetamine* **AMBER shared care protocol
for ADULTS.**

For use between Frimley ICB Primary Care and any Right to Choose (RTC) or Private Provider

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Lisdexamfetamine

Lisdexamfetamine & dexamfetamine are indicated as part of a comprehensive treatment programme for attention-deficit hyperactivity disorder (ADHD) in adults when remedial measures alone prove insufficient. Treatment must be initiated and supervised by a physician specialised in the treatment of ADHD such as an adult psychiatrist.

Diagnosis should be made according to the current DSM criteria or ICD guidelines, and should be based on a complete history and evaluation of the patient.

The specific aetiology of this syndrome is unknown, and there is no single diagnostic test. Adults with ADHD have symptom patterns characterised by restlessness, impatience, and inattentiveness. Symptoms such as hyperactivity tend to diminish with increasing age, possibly due to adaptation, neurodevelopment and self-medication. Inattentive symptoms are more prominent and have a greater impact on adults with ADHD.

Diagnosis in adults should include a structured patient interview to determine current symptoms. The pre-existence of childhood ADHD is required and has to be determined retrospectively (by patients' records or, if not available, by appropriate and structured instruments/interviews). Third-party corroboration is desirable, and treatment should not be initiated when the verification of childhood ADHD symptoms is uncertain. Diagnosis should not be made solely on the presence of one or more symptoms. The decision to prescribe in adults must be based on a very thorough assessment and diagnosis should include moderate or severe functional impairment in at least 2 settings (for example, social, academic, and/or occupational functioning), affecting several aspects of an individual's life.

Use should always be used according to the licensed indication and according to prescribing/diagnostic guidelines.

*** As lisdexamfetamine is a prodrug for dexamfetamine, much of the clinical information is similar , although where there are key differences (including dosing), this information should**

be taken from the relevant SmPC [EMC \(medicines.org.uk\)](https://www.medicines.org.uk) or BNF monograph [Dexamfetamine sulfate | Drugs | BNF | NICE](#). Where lisdexamfetamine is specified, extrapolate to dexamfetamine, unless otherwise stated.

This shared care protocol was adapted from the national RMO template for **lisdexamfetamine**, however, when patients are responding well but cannot tolerate the longer effect profile of lisdexamfetamine they may be considered for off label use of **dexamphetamine**. Lisdexamfetamine was formulated specifically to allow once daily dosing with a consistent treatment effect throughout the day, and *a reduced potential for abuse, overdose toxicity and drug tampering*. Dexamfetamine should not be used where there is a risk of diversion or misuse.

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this 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 provide the appropriate counselling (see section 11) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- 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.
- Transfer to primary care is normally after the patient has been treated at the maintenance dose for **2 months** and with satisfactory investigation results for at **least 4 weeks**. Prescribe sufficient medication (one month's supply) to enable transfer to primary care, including where there are unforeseen delays to transfer of care. Check product details for pack sizes as most products manufactured in boxes of 28 dose units.
- Prescribe in line with controlled drug prescription requirements (Section 6)
- Once treatment is optimised, complete the shared care documentation and send a request to prescribe to patient's GP practice detailing the diagnosis, current and ongoing dose, baseline and most recent test results, confirm the monitoring schedule and when the next monitoring is required. Include contact information (section 13).
- Conduct the required monitoring in section 8 and communicate the results to primary care. 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.
- Reassume prescribing responsibilities if the patient becomes or wishes to become pregnant.
- If the patient develops a concurrent mental health or neurodevelopmental condition requiring specialist care where their ADHD is best managed by the specialist service, reassume prescribing responsibilities, or inform the patient's GP that a referral to an alternative provider is required in order to properly support the patient.
- Provide advice to primary care on the management of adverse effects if required.
- Advise primary care if treatment should be discontinued. Trial discontinuations can be supported by the specialist.

Primary care responsibilities

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.

- If accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5 taking into any account potential drug interactions in section 7.
- Adjust the dose of lisdexamfetamine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9.
- Assess for possible interactions with lisdexamfetamine when starting new medicines (see section 7).
- Manage any adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop lisdexamfetamine and make an urgent referral to the specialist if cerebral ischaemia, new or worsening seizures, or serotonin syndrome are suspected.
- Discuss other adverse effects with the specialist team as clinically appropriate (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.

Patient and/or carer responsibilities

- Not to drive, use other modes of transport that require a high level of alertness e.g. bicycle, scooter, operate machines or undertake skilled tasks if lisdexamfetamine affects their ability to do so safely, e.g. by causing dizziness, drowsiness, or visual disturbances
- Avoid alcohol while taking lisdexamfetamine, as it may make side effects worse. Avoid recreational drugs.
- Take lisdexamfetamine as prescribed and do not stop taking it without speaking to their primary care prescriber or specialist.
- Lisdexamfetamine is a schedule 2 controlled drug. Patients, their family or carer 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. Note that where a child (under 16) presents to a pharmacy to collect their medication, pharmacists will need to decide whether to provide it to them, or request that a family member or carer collects the medicine, based on the individual circumstances.
- Tell anyone who prescribes them a medicine that they are taking lisdexamfetamine.
- Attend regularly for monitoring and review appointments with primary care and specialist. Be aware that medicines may be stopped if they do not attend appointments.
- Report adverse effects to their primary care prescriber. 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 GP and be aware they should discuss the use of lisdexamfetamine with their pharmacist before purchasing any OTC medicines.
- People of child-bearing potential should inform the specialist or GP immediately if they suspect they may be pregnant, or are planning a pregnancy

1. Background

Lisdexamfetamine dimesylate is metabolised following administration to dexamfetamine and therefore has the same sympathomimetic mechanism of action with central stimulant and anorectic activity.

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. It may be offered as a first line pharmacological treatment option for adults with ADHD who have been appropriately diagnosed (see NICE Guidance [NG87 Attention deficit hyperactivity disorder: diagnosis and management](#)). NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.

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.

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.

2. Indications

- Attention deficit hyperactivity disorder (ADHD) in adults when response to previous methylphenidate treatment is considered clinically inadequate or as first line therapy.

3. Locally agreed off-label use

This shared care protocol only supports use of lisdexamfetamine within its licensed indication. The following information should be provided in correspondence to support prescribing in line with this shared care.

- Dosing specific to the indication
- Relevant interaction information
- Any additional monitoring requirements over and above the shared care.
- Duration of treatment
- Frequency of review.
- Specific features of adverse effects or deterioration pertinent to the specific indication for which it is used

4. Contraindications and cautions

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.

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.
- 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).
- 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.
- Depressive symptoms; patients should be screened for risk of bipolar disorder, including psychiatric and family histories.
- Severe renal impairment; GFR 15-30mL/min/1.73m² or CrCl less than 30mL/min, or according to criteria for child's age. Dose reduction is required, see section 5.
- Hepatic insufficiency (due to lack of data).
- Pregnancy or breast-feeding (see section 12).
- Potential for abuse, misuse, or diversion.

5. Initiation and ongoing dose regimen

- Transfer of monitoring and prescribing to primary care is normally between 8 - 12 weeks, and when 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.

Initial stabilisation (lisdexamfetamine): 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 stabilisation period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):. Lisdexamfetamine Adult should be administered orally at the lowest effective dosage.

Maximum dose: The maximum recommended dose is 70 mg/day; higher doses have not been studied; consult [BNF](#) and [SPC](#).

The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

In severe renal impairment: In patients with severe renal insufficiency (GFR 15 to <30 mL/min/1.73 m² or CrCl <30 mL/min) the maximum dose should not exceed 50 mg/day. Further dosage reduction should be considered in patients undergoing dialysis

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, their family or carer, and GP of the outcome.

Unlicensed dexamfetamine use in adults: Initially 5 mg twice daily, dose is increased at weekly intervals according to response, maintenance dose to be given in 2–4 divided doses; maximum 60 mg per day. Use with caution in renal impairment. . [Dexamfetamine sulfate | Drugs | BNF | NICE](#)

6. Pharmaceutical aspects

Route of administration	Oral
Formulation Lisdexamfetamine	Lisdexamfetamine dimesylate 30mg 50mg and 70mg hard capsules (Elvanse Adult®) Lisdexamfetamine dimesylate 20mg, 30mg, 40mg, 50mg, 60mg and 70mg hard capsules (Elvanse®) – use in adults may be considered off-label. See SPC for full details.
Formulation Dexamfetamine	Dexamfetamine sulfate 5mg, 10mg and 20mg immediate release tablets (Amfexa®) Dexamfetamine sulfate 5mg immediate release tablets Dexamfetamine sulfate 5mg/5mL sugar-free oral solution Please note licensed indications vary by manufacturer. See SPCs for full details
Administration details Lisdexamfetamine	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 SPC for further information. If a dose is missed, the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose. Afternoon doses should be avoided because of the potential for insomnia.
Administration details Dexamfetamine	Tablets can be halved Dexamfetamine should not be taken too late after lunch time to avoid disturbances of sleep If a dose is missed, the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose.
Other important information Lisdexamfetamine / dexamfetamine	Lisdexamfetamine is a schedule 2 controlled drug and is subject to prescribing restrictions and has the potential for misuse and diversion. Patients should be advised to avoid alcohol which may exacerbate the central nervous system (CNS) side-effects of lisdexamfetamine. Lisdexamfetamine is subject to additional monitoring by the Medicines and Healthcare products Regulatory Agency (MHRA) and healthcare professionals are encouraged to report any suspected adverse reactions Amfetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amfetamines may interfere with urinary steroid determinations.

7. Significant medicine interactions

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

Lisdexamfetamine

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

- Mono-amine oxidase inhibitors (MAOIs) and other sympathomimetics (e.g. rasagiline, selegiline, safinamide) – 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 amphetamine.
- 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

Dexamfetamine

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

- Mono-amine oxidase inhibitors (MAOIs) and other sympathomimetics (e.g. rasagiline, selegiline, safinamide) – additive hypertensive effect
- Clonidine – increased duration of action of dexamfetamine, reduced antihypertensive action of clonidine

Other clinically significant interactions

- Coumarin anticoagulants, anticonvulsants, selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants (TCAs): metabolism may be inhibited by dexamfetamine. Dose adjustment may be required when starting or stopping dexamfetamine.
- SSRIs (e.g. fluoxetine, paroxetine): may increase exposure to dexamfetamine. Risk of serotonin syndrome.
- Serotonergic drugs, bupropion, tapentadol, tramadol: Risk of serotonin syndrome
- TCAs and nabilone: may increase risk of cardiovascular adverse events.
- Anticonvulsants (e.g. phenobarbital, phenytoin, primidone): Metabolism may be inhibited and absorption may be delayed by dexamfetamine. Dose adjustment may be required when stopping or starting dexamfetamine.
- Antacids (e.g. sodium bicarbonate) and urinary alkalinizing agents (e.g. acetazolamide, some thiazides): may increase exposure to dexamfetamine
- Gastrointestinal acidifying agents (e.g. ascorbic acid, fruit juices) and urinary acidifying agents (e.g. ammonium chloride, sodium acid phosphate): may reduce exposure to dexamfetamine
- Antihistamines: sedative effect may be counteracted
- Antihypertensives, including guanethidine: effects may be reduced by dexamfetamine

- Beta-blockers (e.g. propranolol): risk of severe hypertonia. May reduce effects of dexamfetamine
- Lithium, phenothiazines, haloperidol: may reduce the effects of dexamfetamine
- Disulfiram: may inhibit metabolism and excretion of dexamfetamine
- Opioids: analgesic effects may be increased and the depressant effects (e.g. respiratory depression) may be decreased by dexamfetamine
- Halogenated anaesthetics: risk of sudden blood pressure increase during surgery. Avoid dexamfetamine on the day of planned surgery.
- Cytochrome P450 (CYP450) substrates, inducers or inhibitors: use with caution; role of CYP450 in dexamfetamine metabolism is not known
- Alcohol: may exacerbate adverse CNS effects of dexamfetamine
- Apraclonidine: effects decreased by dexamfetamine
- Ritonavir, tipranavir: may increase exposure to dexamfetamine

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

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 a transfer to primary care for prescribing and monitoring occur.

Pre-treatment (specialist):

- A 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
- A risk assessment for substance misuse and drug diversion
- Blood pressure (BP) and heart rate
- Height, weight and body mass index (BMI)
- Arrange for electrocardiogram (ECG), only if the patient has any of the following:
 - History of congenital heart disease or previous cardiac surgery
 - 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
 - Chest pain suggestive of cardiac origin
 - Signs of heart failure, heart murmur or hypertension
 - Current treatment with a medicine that may increase cardiac risk

Initial monitoring (specialist):

- Assess heart rate and blood pressure after every change of dose
- Weight and height (using centiles as per NICE)
- Assessment for new or worsening psychiatric symptoms following every change of dose
- 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 will be by the specialist, as per local arrangements, and 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.

9. Ongoing monitoring requirements to be undertaken by primary care

See section 10 for further guidance on management of adverse effects/responding to monitoring results. Specialist clinician will monitor until primary care prescriber has agreed to take over prescribing.

Monitoring and actions	Frequency
<ul style="list-style-type: none"> Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms Weight and appetite Assessment for new or worsening psychiatric and neurological signs or symptoms (e.g. tics, anxiety, symptoms of bipolar disorder) Explore whether patient is experiencing any difficulties with sleep 	Every 6 months, and after any change of dose recommended by specialist team.
Assessment of adherence, and for any indication of abuse, misuse, or diversion	As required, based on the patient's needs and individual circumstances
Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD	Annually

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.

10. Adverse effects and other management

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme.

Visit www.mhra.gov.uk/yellowcard

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

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	
Cardiovascular	Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP
	<ul style="list-style-type: none"> In context of recent dose increase, revert to previous dose and discuss with specialist for ongoing management In absence of recent dose changes, reduce dose by half and discuss with specialist or cardiology for further advice.
	Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia,
	Discontinue lisdexamfetamine as soon as possible. Management depends on severity; use clinical judgement and seek advice if necessary.

	incoordination, rigidity, nausea, vomiting, diarrhoea	
Weight or BMI	Anorexia or weight loss, weight or BMI outside healthy range	Exclude other reasons for weight loss. Exclude other reasons for weight loss. Give advice as per NICE NG87 : <ul style="list-style-type: none"> • take medication with or after food, not before • additional meals or snacks early in the morning or late in the evening when stimulant effects have worn off • obtaining dietary advice • consuming high-calorie foods of good nutritional value Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be required.
Gastrointestinal Disorders	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
Psychiatric disorders	New or worsening psychiatric or neuropsychiatric symptoms, e.g. mania, 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
Nervous system disorders	New or worsening seizures	Stop treatment and discuss with specialist. Discontinuation may be indicated.
	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
Suspicion of abuse, misuse, or diversion		Discuss with specialist team

11. Advice to patients and carers

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 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:

- NHS – Attention deficit hyperactivity disorder. <https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/>
- Choice and medication: [Prescribing information | Attention deficit hyperactivity disorder | CKS | NICE](#)
- Royal College of Psychiatrists – ADHD in adults. <https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults>

12. Pregnancy, paternal exposure and breast feeding

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:

<https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-AMFETAMINES-IN-PREGNANCY/>

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.

13. Specialist contact information

Add name of specialist(s) responsible for patient assessment, diagnosis & prescribing recommendation.

1. Name 1 (add qualification)
2. Name 2 (add qualification)
3. Name 3 (add qualification)

Add email address:

Add any alternative contacts:

Add contact phone number:

Add contact days / hours available:

Out of hours contact details: Consider emergency services

If a patient requires additional support, which is not related to their ADHD treatment, then referral via a health, education or social care practitioner, would normally be required.

14. Additional information

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 in writing of any changes to the patient's GP or their contact details.

15. References

- NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via <https://www.nice.org.uk/guidance/ng87/> on 04/05/21
- eBNF. Lisdexamfetamine, last updated 4th September 2020. Accessed via <https://bnf.nice.org.uk/> on 04/05/2021
- 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: 11/01/21. Accessed via <https://www.medicines.org.uk/emc/product/6828/smpc> on 13/05/21
- The Renal Association. CKD Stages. Accessed via <https://renal.org/health-professionals/information-resources/uk-eckd-guide/ckd-stages> on 13/05/21
- NICE. NG46: Controlled drugs: safe use and management. April 2016. Accessed via <https://www.nice.org.uk/guidance/ng46/> on 05/05/2021
- Gov.uk: Drugs and driving: the law Gov.uk. Drugs and driving: the law. Accessed via <https://www.gov.uk/drug-driving-law> on 13/05/21
- 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 13/05/2021
- NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: last revised January 2021. Accessed via <https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/amfetamines/> on 13/05/21

16. Other relevant national guidance

- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from <https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/>
- 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/>

17. Local arrangements for referral

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

- Specialist contacts patient's GP requesting transfer of prescribing and monitoring responsibility as detailed within this shared care. Note: The request to prescribe must be accompanied by sufficient clinical information in order for the patient's GP to be able to consider the appropriateness of the request to prescribe in response to the details of the assessment, diagnosis and medication initiation and stabilisation. Full details can be found here [Request to prescribe following referral to an adult ADHD service](#).
- Specialist completes and signs Appendix 1 & sends to patient's GP (GP may need to forward a copy of shared care document to provider – available here [Frimley ICB Shared Care Documents](#)).

- GP completes Appendix 2 or Appendix 3 as appropriate to confirm their decision and sends to provider.
- GP either takes over prescribing responsibility & monitoring under the shared care arrangements, or if declined, the provider is responsible for ongoing prescribing and monitoring for the individual.
- When seeking specialist advice relating to the management of ADHD for an individual continuing with shared care, see section 13 for contact details.
- If the patient develops a concurrent mental health or neurodevelopmental condition requiring specialist care where their ADHD is best managed by the specialist service, reassume prescribing responsibilities, or inform the patient's GP that a referral to an alternative provider is required in order to properly support the patient's change in condition.

Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear *[insert Primary Care Prescriber's name]*

Patient name: *[insert patient's name]*

Date of birth: *[insert date of birth]*

NHS Number: *[insert NHS Number]*

Diagnosis: *[insert diagnosis]*

As per the agreed **Frimley ICB shared care protocol** for *[insert medicine name]* for the treatment of *[insert indication]*, this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care, and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out. I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
<i>The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:</i>	
<i>Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory</i>	Yes / No
<i>The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care</i>	Yes / No
<i>The risks and benefits of treatment have been explained to the patient</i>	Yes / No
<i>The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed</i>	Yes / No
<i>The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments</i>	Yes / No
<i>I have enclosed a copy of the shared care protocol which covers this treatment</i>	Yes / No
<i>I have included with the letter, copies of the information the patient has received</i>	Yes / No
<i>I have provided the patient with sufficient medication to last until</i>	
<i>I have arranged a follow up with this patient in the following timescale</i>	

Treatment was started on *[insert date started]* and the current dose is *[insert dose and frequency]*.

If you are in agreement, please undertake monitoring and treatment from *[insert date]* NB: *date must be at least 1 month from initiation of treatment.* The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible.

Specialist* signature: _____

Specialist name (PRINT): _____

Specialist qualification(s): _____

Date: _____

* A healthcare professional with training and expertise in managing ADHD. This may include a consultant, doctor, nurse or pharmacist specialising in diagnosing and managing ADHD.

Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist)

Primary Care Prescriber Response

Dear *[insert Doctor's name]*
Patient *[insert Patient's name]*
NHS Number *[insert NHS Number]*
Identifier *[insert patient's date of birth and/or address]*

Thank you for your request to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & frequency

I can confirm that I am willing to take on this responsibility from *[insert date]* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

DELETE IF NOT APPLICABLE: I shall be working within the Frimley ICB Locally Commissioned Service for adults with ADHD and will provide both the 6 month physical health check and the annual medication review within primary care. (There should, therefore, be no further charges once I agree to take over prescribing this patient's medication). If the patient's condition should change sufficiently that I require specialist input, I shall contact you for advice and guidance, for which the review rate may be charged.

Primary Care Prescriber signature: _____

Primary Care Prescriber name (PRINT): _____

Date: _____

Primary Care Prescriber address/practice stamp

Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

Re:

Patient *[insert Patient's name]*
NHS Number *[insert NHS Number]*
Identifier *[insert patient's date of birth and/or address]*

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety, NHS Frimley ICB, in conjunction with local acute trusts have classified *[insert medicine name]* as a Shared Care medication, and requires a number of conditions to be met before transfer can be made to primary care.

Shared care is a term used within the NHS to describe the situation where a specialist doctor wishes to pass some of the patient’s care, such as prescription of medication, over to their general practitioner (GP). This is something that can be requested but the guidance is that this may only be done if the GP agrees. The GP will need to consider a number of factors to decide if this is safe.

If care is transferred, from this point the primary care prescriber will be responsible for the prescriptions they sign. The GMC states that when taking on prescribing, all clinicians must keep informed about the medications they prescribe. They need to be able to recognise serious and adverse side effects and ensure that appropriate clinical monitoring arrangements are in place. They must also ensure adequate monitoring. This is a significant responsibility and decisions must be made carefully bearing this in mind.

GPs need to be mindful of focussing on undertaking essential services to put patients first and foremost before agreeing to take on extra work; not working beyond their competences or over safety limits.

If a GP feels that it is not appropriate for any reason for them to take over this extra work, then appropriate arrangements for the continuing care of the patient would be as a default that the prescribing should remain with the specialist service.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail.

Yours sincerely

Primary Care Prescriber signature: _____

Primary Care Prescriber name (PRINT): _____

Date: _____

Primary Care Prescriber address/practice stamp