NHS
Telford and Wrekin
Clinical Commissioning Group

Lisdexamfetamine (Elvanse® ▼)
For children of 6 years of age and older with Attention Deficit Hyperactivity Disorder (ADHD)
Effective Shared Care Agreement

Patient details

Name: _____

Address: _____

Date of Birth: _____

NHS number: _____

Contact details

Specialist:
Address:

Email:

Contact number:

GP

Address:

Email:

Contact number:

Patient

Name:

Contact number:

Agreement to shared care, to be signed by GP and Specialist before prescribing is transferred to GP

Specialist Signature: _____

Date: _____

GP Signature: _____

Date: _____

Patient Signature: _____

Date: _____

This Effective Shared Care Agreement outlines suggested ways in which the prescribing responsibilities can be shared between the specialist and GP. GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient's health remains with the specialist.
If a specialist asks the GP to prescribe, the GP should reply to this request within 2 weeks

The prescriber of the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Responsibilities of the specialist initiating treatment

- Discuss with the patient/parent/guardian options for treatment and the suitability of lisdexamfetamine
- Discuss the potential benefits and side effects of treatment with the patient/parent/guardian
- Monitor treatment (baseline and annually) - height, weight, appetite, pulse and blood pressure; emergence of /worsening of pre-existing psychiatric disorders; risk of diversion/misuse/abuse.
- Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient/parent/guardian.
- Titrate lisdexamfetamine to an effective dose. If both GP and Specialist feel it is appropriate, shared care may be initiated before the patient is stabilised on the effective dose, as long as the dose is stable until the next Specialist appointment.
- Ensure agreed signed shared care form has been received back from GP to indicate that the GP is in agreement with prescribing and monitoring.
- Communicate to the GP re-established regimen; follow up arrangements and when to refer back.
- Communicate promptly with the GP when treatment is changed.
- Annual supervision and assessment of the patient during a drug holiday.
- To obtain school and parental/carer's reports to assist with the assessment of the patient's progress.
- Have a mechanism in place to receive rapid referral of a patient from the GP in the event of adverse effects or deteriorating clinical condition.
- To provide guidance to teachers regarding treatment with parental consent.
- Notify GP of review date (at least annually), and give advice on stopping treatment.
- Report adverse events to the MHRA (via Yellow Card)
- Ensure that clear backup arrangements exist for GPs to obtain advice and support.

Responsibilities of the General Practitioner

- Notify the specialist in writing within 2 weeks if they agree with this Shared Care Agreement.
- Prescribe the lisdexamfetamine at the dose recommended, from the agreed date.
- Adjust the dose as advised by the specialist.
- Review patient annually between consultant appointments.
- Monitor treatment - height, weight, appetite, pulse and blood pressure; emergence of /worsening of pre-existing psychiatric disorders; risk of diversion/misuse/abuse. Monitor for adverse drug reactions/interactions
- Report to & seek advice from the specialist on any aspect of patient care of concern to the GP that may affect treatment.
- Refer back to specialist if the patient's condition deteriorates, or if there are concerns over patient compliance.
- Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
- Report adverse events to the MHRA (via Yellow Card)

Responsibilities of the Patient/Carer's

- Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
- Share any concerns in relation to treatment with lisdexamfetamine.
- Inform specialist or GP of any other medication being taken, including over-the-counter products.
- Inform specialist if any changes in symptoms or behaviour occur.
- Report any adverse effects or warning symptoms to the specialist or GP whilst taking lisdexamfetamine.

General information on lisdexamfetamine

Licensed Indication

Lisdexamfetamine is indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate.

Unlicensed Indication

As above for adults over 18 years of age.

Dosage and administration

Lisdexamfetamine is a pharmacologically inactive prodrug. After oral administration, lisdexamfetamine is rapidly absorbed from the gastrointestinal tract and hydrolysed primarily by red blood cells to dexamfetamine.

DOSE: The starting dose for all patients is 30mg once daily in the morning. This may be increased at approximately weekly intervals by 20mg increments, to a maximum of 70mg once daily. The lowest effective dose should be administered. Lisdexamfetamine may be taken with or without food. The capsules should be swallowed whole or opened, the contents dispersed in a glass of water (stir until completely dispersed) and the resulting solution swallowed immediately (a film of inactive ingredients may remain in the glass). Afternoon doses should be avoided (risk of insomnia). If there is a missed morning dose, wait until the following morning before administering the next dose. Treatment should be stopped if the symptoms do not improve after 1 month at an appropriate dose. Reduce the dosage if paradoxical aggravation of symptoms/other intolerable adverse events emerge.
NB: Lisdexamfetamine is classified as a Schedule 2 controlled drug. All prescriptions should be appropriately written to avoid dispensing delays**.**

Contraindications

Hypersensitivity to sympathomimetic amines or any of the excipients: concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days after MAOI treatment, hyperthyroidism or thyrotoxicosis, agitated states, symptomatic cardiovascular disease, advanced arteriosclerosis, moderate to severe hypertension, glaucoma.

CAUTIONS: in patients with a history of substance abuse or dependence; should not be used if there are 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. Caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate. Cardiomyopathy has been reported. All patients should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such disease. Patients who develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation. Administration may exacerbate symptoms of behaviour disturbance and thought disorder in patients with pre-existing psychotic disorders. Take particular care in patients with comorbid bipolar disorder. Screen patients with comorbid depressive symptoms to determine if they are at risk for bipolar disorder before lisdexamfetamine treatment is started. If treatment emergent psychotic or manic symptoms occur, consideration should be given to a possible causal role of the stimulant, and possible discontinuation of treatment. Patients beginning treatment for ADHD should be monitored for the appearance/worsening of aggressive behaviour or hostility. Clinical evaluation for tics and Tourette's syndrome in children and their families should precede use. Growth should be monitored during treatment with stimulants, and patients who are not growing/ gaining weight as expected may need to have their treatment interrupted. In the presence of new onset or worsening seizures, lisdexamfetamine should be discontinued. Difficulties with accommodation and blurring of vision have been reported with stimulant treatment. Use with caution in patients taking other sympathomimetic drugs

Side effects

Very common: decreased appetite, insomnia, headache, dry mouth (adult), upper abdominal pain (6-12 yr), weight decreased (6-17 yr); common: anorexia, tic (6-12 yr), affect lability (6-17yr), psychomotor hyperactivity (6-12yr, adults), aggression (6-12yr), dizziness, restlessness (adult), tremor (13-17yr, adult), somnolence (6-12yr), mydriasis (6-12yr), tachycardia (13-17yr, adult), palpitation (13-17 yr, adult), dyspnoea (13-17yr, adult), dry mouth (6-17yr), diarrhoea, upper abdominal pain (13-17yr, adult), nausea, vomiting, (6-17yr), hyperhidrosis (adult), rash (6-12yr), erectile dysfunction (adult), irritability, fatigue, feeling jittery (adult), pyrexia (6-12yr), increased blood pressure (13-17, adults), decreased weight (adult). See SPC for a full list of adverse effects that had a frequency occurrence of uncommon/rare or where the frequency was not known.

Drug Interactions[1]

Amfetamines should not be administered during or within 14 days following the administration of **monoamine oxidase inhibitors (MAOI)** because they can increase the release of norepinephrine and other monoamines. This can cause severe headaches and other signs of hypertensive crisis. A variety of toxic neurological effects and malignant hyperpyrexia can occur, sometimes with fatal outcomes. **Chlorpromazine** blocks dopamine and norepinephrine receptors, thus inhibiting the central stimulant effects of amfetamines. **Haloperidol** blocks dopamine receptors, thus inhibiting the central stimulant effects of amfetamines. The anorectic and stimulatory effects of amfetamines may be inhibited by lithium carbonate. Amfetamines potentiate the analgesic effect of **narcotic analgesics.** Amfetamines may decrease the effectiveness of **guanethidine** or other **antihypertensive** medications. **Ascorbic acid** and other agents and conditions (diets high in fruits and vegetables, urinary tract infections and vomiting) that acidify urine increase urinary excretion and decrease the half-life of amfetamine. **Sodium bicarbonate** and other agents and conditions (**thiazide diuretics**, diets high in animal protein, diabetes, respiratory acidosis) that alkalinise urine decrease urinary excretion and extend the half-life of amfetamine. There are limited data on the possible interaction with **alcohol**. Amfetamines can cause a significant elevation in plasma **corticosteroid** levels. It may interfere with urinary steroid determinations. In vitro experiments with human microsomes indicate minor inhibition of **CYP2D6** by amfetamine and minor inhibition of **CYP1A2, 2D6**, and **3A4** by one or more metabolites. Although the clinical significance of this interaction is likely to be minimal, consideration should be given when medications metabolised by these pathways are administered.

There are numerous drug interactions and the Summary of Product Characteristics (www.medicines.org.uk) should be consulted both before treatment and when new drugs are introduced.

[1] BNF 68 September 2014-March 2015.