

SHARED CARE GUIDELINES

Lisdexamfetamine for ADHD in Children and Adolescents

It is vital for safe and appropriate patient care that there is a clear understanding of where clinical and prescribing responsibility rests between Consultants and General Practitioners (GPs).

This guideline reinforces the basic premise that:

- When clinical and / or prescribing responsibility for a patient is transferred from hospital to GP, the GP should have full confidence to prescribe the necessary medicines. Therefore, it is essential that a transfer of care involving medicines that a GP would not normally be familiar with, should not take place without the “sharing of information with the individual GP and their mutual agreement to the transfer of care.”

These are not rigid guidelines. On occasions, Consultants and GPs may agree to work outside of this guidance. As always, the doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

Licensed indication: Lisdexamfetamine is licensed for the treatment of attention-deficit hyperactivity disorder (ADHD) for children over 6 years as part of a comprehensive treatment programme when response to previous methylphenidate treatment is considered clinically inadequate. Treatment must be under the supervision of a specialist in childhood behavioural disorders.

Lisdexamfetamine is a second line medication used in patients who have partially responded to methylphenidate at maximum dose and who require a once daily formulation.

Dosage and administration: Strength and form: 20mg, 30mg, 40mg, 50mg, 60mg, 70mg capsules

Dose range: Initially 30 mg once daily in the morning, increased if necessary at weekly intervals by 20 mg; maximum 70 mg daily.

Administration:

One capsule to be taken in the morning, preferably after breakfast due to appetite suppression.

Afternoon doses should be avoided due to risk of insomnia. If there is a missed dose, wait until the following morning before administering the next dose.

The capsule can be opened and dissolved in yoghurt, orange juice or water stirred until fully dispersed and the whole glass should be drunk immediately. It should not be stored.

Note that increasing the dose does not prolong its effect.

Cautions and contraindications:

Lisdexamfetamine is contra-indicated in children with hypersensitivity to sympathomimetic amines or any of the excipients; concomitant use of monoamine oxidase inhibitors (MAOIs) or within 14 days after MAOI treatment, hyperthyroidism or thyrotoxicosis, agitated states, symptomatic cardiovascular disease, advanced arteriosclerosis, moderate to severe hypertension, glaucoma.

Caution is required in children with epilepsy, a history of drug or alcohol dependence or symptoms or family history of tics or Tourette’s syndrome. Stimulants have the potential for abuse, misuse, dependence or diversion. Monitor psychiatric status as treatment may exacerbate symptoms of behaviour disturbance and thought disorder particularly in co-morbid bipolar disorder. Lisdexamfetamine is associated with worsening pre-existing anxiety, agitation or tension.

Stimulant products generally should not be used 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 drug.

Monitor cardiovascular status as sudden cardiac or unexplained death has been reported.

Use in pregnancy only if potential benefit outweighs risk.

Avoid breast feeding if on lisdexamfetamine as it can be present in human milk.

In renal impairment (CrCl<30mL/min), maximum dose should be 50mg/day.

Monitoring requirements:

Baseline monitoring

Baseline evaluation of a patient's cardiovascular status including blood pressure, heart rate and cardiovascular examination.

Family history of sudden cardiac/unexplained death.

Past and present co-morbid medical and psychiatric disorders or symptoms.

Pre-treatment height and weight on a growth chart.

Consistent with other stimulants, the potential for abuse, misuse or diversion of lisdexamfetamine should be considered prior to prescribing.

Ongoing monitoring

Growth, psychiatric, and cardiovascular status should be continually monitored:

- Blood pressure and pulse should be recorded on a centile chart at each adjustment of dose and at least every six months.
- Weight should be recorded every 3 months in children 10 years and under.
- Height, weight, and appetite should be recorded at least six-monthly with maintenance of a growth chart.
- Development of *de novo* or worsening of pre-existing psychiatric disorders should be monitored at every adjustment of dose and then at least every six months and at every visit.
- Patients should be monitored for the risk of diversion, misuse, and abuse of lisdexamfetamine.

Routine blood tests are not needed. This monitoring should occur as part of the specialist clinic.

Action to be taken if abnormal results/adverse effects: In the event of any adverse effects the specialist clinic should write a management plan and this will be shared with primary care. If adverse events are detected in a primary care setting then the specialist should be informed as soon as possible. Healthcare professionals should report any suspected adverse reactions via the Yellow Card Scheme.

Drug interactions: Lisdexamfetamine may interact with extended release guanfacine, extended release venlafaxine, ascorbic acid, sodium bicarbonate, MAOI, antihypertensives, narcotic analgesics, chlorpromazine, haloperidol, lithium carbonate. For full information see current edition of BNFc.

Adverse Effects: nausea, decreased appetite, vomiting, diarrhoea, dry mouth, abdominal cramps, dyspnoea, sleep disturbances, tics, aggression, headache, dizziness, drowsiness, mydriasis, labile mood, weight loss, pyrexia, malaise and growth restriction in children.

Less common unwanted effects include anorexia, tachycardia, palpitation, hypertension, logorrhoea, anxiety, paranoia, restlessness, depression, dysphoria, dermatillomania, mania, hallucination, sweating, tremor, visual disturbances, sexual dysfunction, rash, angle-closure glaucoma, cardiomyopathy, euphoria and seizures; central stimulants have provoked choreoathetoid movements, dyskinesia and Tourette's syndrome in predisposed individuals. For full information see current edition of BNFc.

Specialist responsibilities:

1. Confirm the diagnosis of ADHD following full assessment, drawing upon information from all sources including diagnostic criteria such as DSM V and first hand observations of the child. Communicate details of the diagnosis to the GP.
2. Confirm inadequate clinical response to methylphenidate
3. Ensure baseline monitoring of height, weight, BP has been performed plus any additional relevant investigations as described above. Communicate the results of this, and subsequent monitoring to the GP.
4. Decisions to initiate treatment should only be made by consultants or associate specialists. We recommend that stimulant medications are only used under consultant or associate specialist supervision.
5. Prescribe 1 month of lisdexamfetamine for a trial period and discontinue if no response to maximum dose of 70mg or significant adverse effect.
6. The primary purpose of review is to monitor efficacy of the treatment at least annually and consider

whether continuation of treatment is appropriate.

7. Review patient at regular intervals, initially 4-6 weeks after starting medication. Children maintained on effective medication will be seen at least every 6 months and more frequently if needed.
8. Undertake any necessary monitoring at review appointments (height, weight, BP, pulse at least every 6 months as described in monitoring above).
9. Arrange shared care with the GP once stabilised on medication.
10. Adjust treatment as appropriate such as varying dosage, or use for a trial period. This would include periodic suspension of treatment to assess the child's condition.
11. Stop treatment when appropriate. In particular there will usually be a period without medication on leaving school. A plan should be formulated to stop treatment or agree who will manage care upon transition from children's to adult-based service.
12. Maintain regular and prompt communications with primary care on each attendance.
13. Communicate all DNAs to the GP

GP responsibilities:

1. Initial referral to a Consultant Community Paediatrician via the school nurse on the ADHD pathway, or Consultant Child and Adolescent Psychiatrist raising the possibility of ADHD.
2. Report any adverse effects of medication to consultant.
3. Provide the patient with monthly repeat prescriptions of medication once the specialist has recommended continuation therapy following the trial period. The patient should allow at least 48 hours for the prescription from the GP to be generated once they have agreed to take on prescribing.
4. Not to initiate or change the ADHD medication without referral to the Consultant.
5. Contact the specialist if they do not agree with the treatment recommendation, or if there is a perceived problem with compliance or concordance, or if they have any questions about the management plan.

Secondary care review: Patients will be reviewed at regular intervals, initially 4-6 weeks after starting medication. Children maintained on effective medication will be seen at least every 6 months and more frequently if needed, or if requested to review by the GP.

Availability: Lisdexamfetamine dimesylate (Elvanse) capsules available in packs of 28:
20mg x 28 = £54.62, 30mg x 28 = £58.24, 40mg x 28 = £62.82, 50mg x 28 = £68.60, 60mg x 28 = £75.18,
70mg x 28 = £83.16 (BNFc Sept 2017)

Back up advice and support:	Specialist	Telephone/Fax	Email address:
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