

## Atomoxetine 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:

Atomoxetine is licensed for the treatment of attention-deficit hyperactivity disorder (ADHD) for children over 6 years as part of a comprehensive treatment programme. It can be used in children less than 6 years of age off license. Treatment must be under the supervision of a specialist in childhood behavioural disorders.

Atomoxetine is usually used as second-line medication following methylphenidate and behavioural modification.

### Dosage and administration:

#### **Child over 6 years (body-weight under 70 kg)**

Initially 500 micrograms/kg daily for 7 days then increased according to response to usual maintenance dose 1.2 mg/kg daily. Higher dose unlikely to be beneficial.

#### **Child (body-weight over 70 kg)**

Initially 40 mg daily for 7 days then increased according to response to usual maintenance dose 80 mg daily; maximum dose 100 mg daily.

Total daily dose may be given *either* as a single dose in the morning *or* in 2 divided doses with last dose no later than early evening.

### Contra-indications:

Narrow angle glaucoma, pheochromocytoma or a history of pheochromocytoma. Atomoxetine should not be used in patients with severe cardiovascular or cerebrovascular disorders whose condition would be expected to deteriorate if they experienced increases in blood pressure or heart rate that could be clinically important.

### Cautions:

Cardiovascular disease including hypertension and tachycardia; QT-interval prolongation (avoid concomitant administration of drugs that prolong QT-interval, and use with caution if there is a family history of QT prolongation). History of seizures.

Hepatic disorders: following rare reports of hepatic disorders, the Medicines and Healthcare products Regulatory Agency (MHRA) has advised that children and carers should be advised of the risk and be told how to recognise symptoms.

Prompt medical attention should be sought in case of abdominal pain, unexplained nausea, malaise, darkening of the urine or jaundice.

Suicidal ideation: following reports of suicidal thoughts and behaviour, the Medicines and Healthcare products Regulatory Agency (MHRA) has advised that patients and their carers should be informed about the risk and told to report clinical worsening, suicidal thoughts or behaviour, irritability, aggression, agitation, or depression. For full information see the current edition of the British National Formulary for Children (BNFc)

### Adverse effects:

For full information see the current edition of the British National Formulary for Children (BNFc).

### Monitoring requirements:

Routine blood tests are not needed. Children treated with atomoxetine should have their height and weight checked, recorded and plotted every 6 months. Blood pressure and pulse should be checked 6 monthly. 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.

**Drug interactions:** There are many possible drug interactions but very few with medicines that may be used in children. Caution should be exercised with concomitant use with methadone, amiodarone, disopyramide,

procainamide, parenteral erythromycin, moxifloxacin, paroxetine, MAOIs, tricyclic antidepressants, mefloquine, antipsychotics, beta-blockers, diuretics and parenteral salbutamol.

For full information see the current edition of the BNFc.

**Specialist responsibilities:**

1. Confirm the diagnosis of ADHD following full assessment, drawing upon information from all sources including diagnostic criteria such as DSM IV and first hand observations of the child. Communicate details of the diagnosis to the GP.
2. Ensure baseline monitoring of height, weight, BP has been performed plus any additional relevant investigations. Communicate the results of this, and subsequent monitoring to the GP.
3. Decisions to initiate treatment should only be made by consultants or staff and associate specialists (SAS). We recommend that atomoxetine is only used under consultant or SAS grade supervision.
4. Trial for 1 to 2 months and discontinue if no response or significant adverse effect.
5. The primary purpose of review is to monitor efficacy of the treatment at least annually and consider whether continuation of treatment is appropriate.
6. Review patient at regular intervals, initially 6 to 8 weeks after starting medication. Children maintained on effective medication will be seen at least every 6 months and more frequently if needed.
7. Undertake any necessary monitoring at review appointments (height, weight, at least every 6 months, BP annually).
8. Arrange shared care with the GP once stabilised on medication.
9. Adjust treatment as appropriate such as varying dosage or timing, or use for a trial period. This would include periodic suspension of treatment to assess the child's condition.
10. 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.
11. Maintain regular and prompt communications with primary care on each attendance.
12. Where a patient does not attend routine follow up appointment(s) a letter should be sent from the specialist to the GP, specifically indicating whether the GP should stop a patient's repeat prescription.

**GP responsibilities:**

1. Initial referral to a Consultant Community Paediatrician or Consultant Child and Adolescent Psychiatrist raising the possibility of ADHD. It is recognised however that many referrals come through the school health service. If the GP does refer a child, information from school is an essential part of the referral.
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.

**Patient and parent/carer responsibilities:**

- Agree to request prescriptions from the GP in good time; obtain the first GP prescription within 2 weeks of being informed that shared care will be in operation.
- Report any concerns or adverse effects to the GP, Paediatrician or Pharmacist.

**Secondary care review:**

Patients will be reviewed at regular intervals, initially 6 to 8 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: 7 day initiation packs (10,18,25 & 40mg)

28 day maintenance packs (10,18,25,40 & 60mg)

28 day maintenance pack (80,100mg)

See [online BNF](#) for current prices

Back up advice and support	Specialist	Telephone/Fax	Email address
Dr Jez Fellick	Consultant Community Paediatrician	0151 482 7874	<a href="mailto:jfellick@nhs.net">jfellick@nhs.net</a>

**Written By** Neil Caldwell, Consultant Pharmacist, Children's Services

Helen Dingle, Prescribing Adviser, Wirral Medicines Management Team, Midlands & Lancashire CSU