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| Atomoxetine Shared Care Guideline: Prescribing Agreement for Attention Deficit Hyperactivity Disorder in Children & Young People (6-18 years) |
| **Section A: To be completed by the hospital specialist initiating the treatment** |
| **GP Practice Details:*****(IT add full GP address, practice code etc)*** | **Patient Details: (IT add patient fields)**Name: Address: DOB: Hospital number: NHS number:  |
| **Specialist prescriber name:** ……………………………...... **Clinic name:**………………………………….**Contact details**: Address: .........................................................................................................................Tel no: ……………………………………… E-mail: …………………………… |
| **Diagnosis: (IT add latest diagnosis)** | **Medication name, dose and frequency to be prescribed by GP:** ………………………………………………. |
| **Next hospital appointment:**  |
| Dear Dr. …………………….,Your patient was reviewed on *;* they started (insert medication name and dose) on  for the above diagnosis and in my view, their condition is now stable. I am requesting your agreement to sharing the care of this patient from  in accordance with the attached Shared Care Prescribing Guideline (approval date ). Please take particular note of the responsibilities for the specialist, GP and patient for this shared care arrangement are detailed. Patient information has been given outlining potential aims and side effects of this treatment. The patient has given me consent to treatment possibly under a shared care prescribing agreement (with your agreement) and has agreed to comply with instructions and follow up requirements.Report all adverse effect of atomoxetine to the MHRA via the yellow card system..The most recent investigations have been performed on  and are acceptable for shared care. Please monitor:Blood pressure, pulse, and weight every 6 monthsFor children 10 years and underweight every 3 months.For children over 10 years weight at 3 and 6 months after starting treatment and every 6 months thereafter. For signs of liver toxicity with atomoxetine.Please re-refer the patient or seek specialist advice from the psychiatrist or paediatrician if there is deterioration in ADHD symptomatology, behaviour, evidence of suicidal ideation or adverse effects of medication.

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| --- | --- | --- | --- | --- |
| **Test** | **Baseline** | **Date** | **Current** | **Date** |
| Blood pressure |  |  |  |  |
| Pulse |  |  |  |  |
| Weight (including centiles) |  |  |  |  |
| Height (including centiles) |  |  |  |  |

Other relevant information: ………………………………………………………………………………………..Specialist Signature: ………………………………………………Date:  |

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# Atomoxetine Shared Care Guideline: Prescribing Agreement for Attention Deficit Hyperactivity Disorder in Children & Young People (6-18 years)

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| NOTES to the GPThe expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing this medicine. The questions below will help you confirm this: * Is the patient’s condition predictable or stable?
* Do you have the relevant knowledge, skills, and access to equipment to allow you to monitor treatment as indicated in this shared care prescribing guideline?
* Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility. Prescribe a maximum of 30 days at a time with a review date of every 6 months. Quantities should be supplied in line with pack size and local waste reduction program. If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should write to the specialist prescriber within 14 days, outlining your reasons for NOT prescribing. If you do not have the confidence to prescribe, we suggest you discuss this with your local Trust/specialist service, who will be willing to provide training and support. If you still lack the confidence to accept clinical responsibility, you still have the right to decline. Your CCG pharmacist will assist you in making decisions about shared care.It would not normally be expected that a GP would decline to share prescribing on the basis of cost. **The patient’s best interests are always paramount** |

Approved by: Integrated medicines committee (IMOC)

Approval date 27th November 2024

Review Date: November 2026

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| Atomoxetine for attention deficit hyperactivity disorder (ADHD) in Children & Young People **(6-18 years)** |
| **Specialist prescriber responsibilities*** Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol ([section 2](#Two_indications)) 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](#Eleven_advice_to_patients)) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet. <https://www.choiceandmedication.org/swlstg-tr/printable-leaflets/patient-information-leaflets/11/ALL/>
* 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](#Four_cx_and_cautions)) and interactions (see [section 7](#Seven_interactions)).
* Conduct required baseline investigations and initial monitoring (see [section 8](#Eight_specialist_monitoring)).
* Initiate and optimise treatment as outlined in [section 5](#Five_dosing). Prescribe the maintenance treatment for at least 4 weeks and until optimised.
* Once treatment is optimised, complete the shared care documentation and send to patient’s GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information ([section 13](#Thirteen_specialist_contact)).
* Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
* Conduct the scheduled reviews and monitoring in [section 8](#Eight_specialist_monitoring) and communicate the results to primary care. After a review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 9](#Nine_primary_care_monitoring) remains appropriate.
* 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*** Respond to the request from the specialist for shared care in writing within 14 days.
* If accepted, prescribe ongoing treatment as detailed in the specialist’s request and as per section 5, taking into account any potential drug interactions in [section 7](#Seven_interactions).
* Adjust the dose of Atomoxetine prescribed as advised by the specialist.
* Conduct the required monitoring as outlined in [section 9](#Nine_primary_care_monitoring). Communicate any abnormal results to the specialist.
* Manage adverse effects as detailed in [section 10](#Ten_ADRs_and_Management) and discuss with specialist team when required.
* Stop atomoxetine and make an urgent referral for appropriate care if cerebral ischaemia or new or worsening seizures occur.
* Refer the management back to the specialist if the patient becomes or plans to become pregnant.
* Stop treatment as advised by the specialist.

**Patient and/or carer responsibilities*** Take Atomoxetine as prescribed and avoid abrupt withdrawal unless advised by the 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 primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in [section 11](#Eleven_advice_to_patients).
* Report the use of any over the counter (OTC) medications to their primary care prescriber and be aware they should discuss the use of Atomoxetine with their pharmacist before purchasing any OTC medicines.
* Atomoxetine is subject to drug driving laws. Not to drive, cycle or operate machines if atomoxetine affects their ability to do so safely, e.g. by causing fatigue, somnolence, and dizziness and to inform the DVLA if their ability to drive safely is affected. See <https://www.gov.uk/adhd-and-driving> and [section 11](#Eleven_advice_to_patients).
* Avoid alcohol while taking Atomoxetine, as it may make some side effects worse. Avoid recreational drugs.
* 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](#Responsibilities)
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| Atomoxetine is a sympathomimetic medicine indicated for the treatment of attention deficit hyperactivity disorder (ADHD). It is an alternative treatment option in patients who cannot tolerate Lisdexamfetamine or methylphenidate, or whose symptoms have not responded to separate 6-week trials of Lisdexamfetamine or methylphenidate (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. Atomoxetine is licensed for Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older, in adolescents and in adults. Atomoxetine should be used as part of a comprehensive treatment programme, typically including psychological, educational, and social measures. Long-term usefulness of atomoxetine for extended periods (over 12 months) should be periodically re-evaluated for the individual patient. 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.Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if a need for ongoing treatment is anticipated. NICE Guidance NG43 Transition from children to adults’ services for young people using health or social care services should be followed.Long-term usefulness of atomoxetine for extended periods (over 12 months) should be periodically re-evaluated for the individual patient. 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. |
| **2. Indications** [Back to top](#Responsibilities) |
| Atomoxetine is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme.To be considered if Methylphenidate or Lisdexamfetamine has not been successful for a 6-week trial at adequate doses or not tolerated. |
| **3. Locally agreed off-label use** [Back to top](#Responsibilities) |
| Not applicable |
| **4. Contraindications and cautions** [Back to top](#Responsibilities)This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see [BNF](https://bnf.nice.org.uk/drug/ciclosporin.html) & [SPC](https://www.medicines.org.uk/emc/search?q=ciclosporin) for comprehensive information. |
| **Contraindications:*** Hypersensitivity to the active substance or to any of the excipients
* During treatment with monoamine oxidase inhibitors (MAOI), or within 14 days of discontinuing those medicines, due to the risk of hypertensive crisis
* Narrow angle glaucoma
* Severe cardiovascular or cerebrovascular disorders, including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias, disorders caused by the dysfunction of ion channels, cerebral aneurysm, or stroke.
* History of phaeochromocytoma

**Cautions:*** Psychiatric and neuropsychiatric symptoms or disorders, including psychotic symptoms, aggressive or hostile behaviour, emotional lability, suicide-related behaviour (suicide attempts or suicidal ideation), motor or verbal tics, anxiety, depressive symptoms, and mania.
* Known serious structural cardiac abnormalities; consultation with a cardiac specialist required before treatment.
* Underlying medical conditions which could be worsened by increases in blood pressure and heart rate, including hypertension, tachycardia, or cardiovascular or cerebrovascular disease.
* Prolonged QT interval (congenital or acquired, e.g., drug-induced) or family history of QT prolongation.
* Any condition that may predispose patients to hypotension or conditions associated with abrupt heart rate or blood pressure changes (risk of orthostatic hypotension)
* Concomitant medications that elevate blood pressure: assess for neurological signs and symptoms at every monitoring visit.
* Other conditions that may precipitate or otherwise induce cerebrovascular conditions: assess for neurological signs and symptoms at every monitoring visit.
* Hepatic insufficiency; dose adjustments required, see [section 5](file:///C%3A%5CUsers%5CEsther-Njane%5CDownloads%5CB1621_ii_atomoxetine-for-patients-within-adult-services.docx#Five_dosing).
* History of seizures
* Susceptibility to angle-closure glaucoma
* Known CYP2D6 poor metaboliser genotype. Dose reduction required, see [section 5](file:///C%3A%5CUsers%5CEsther-Njane%5CDownloads%5CB1621_ii_atomoxetine-for-patients-within-adult-services.docx#Five_dosing).
 |
| **5. Initiation and ongoing dose regime** [Back to top](#Responsibilities)* Transfer of monitoring and prescribing to primary care is after at least **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 bethe responsibility of the specialist prescriber.
 |
| **Initial stabilisation:****Paediatric population up to 70kg body weight**Initiated at a total daily dose of approximately 0.5 mg/kg. The initial dose should be maintained for a minimum of 7 days prior to upward dose titration according to clinical response and tolerability. **Paediatric population above 70kg body weight**Atomoxetine should be initiated at a total daily dose of 40mg. The initial dose should be maintained for a minimum of 7 days prior to upward dose titration according to clinical response and tolerability. **The loading period** **must be prescribed by the initiating specialist.****Maintenance dose (following initial stabilisation):****Paediatric population up to 70kg body weight**The recommended maintenance dose is approximately 1.2 mg/kg/day (depending on the patient's weight and available dosage strengths of atomoxetine). No additional benefit has been demonstrated for doses higher than 1.2 mg/kg/day, but doses increased to 1.8mg/Kg/daily (max 120mg/daily), should be under the direction of a specialist. **Paediatric population above 70kg body weight**The recommended maintenance dose is 80mg, the maximum recommended total daily dose is 120 mg. The safety of single doses over 120mg and total daily doses > 150mg have not been systematically evaluated.**The initial maintenance dose must be prescribed by the initiating specialist.**Atomoxetine does not produce a quick change in symptoms. Onset of action is gradual and is generally seen within three to six weeks but can sometimes take longer.**Conditions requiring dose adjustment:**Hepatic insufficiency: * moderate hepatic insufficiency ([Child-Pugh](https://www.sps.nhs.uk/articles/what-is-the-child-pugh-score/) Class B) reduce starting and target doses to 50% of usual (reduce dose by half, i.e. starting dose should be 20mg daily, and total daily dose should not exceed 50mg daily)
* severe hepatic insufficiency ([Child-Pugh](https://www.sps.nhs.uk/articles/what-is-the-child-pugh-score/) Class C) reduce starting and target doses to 25% of usual (reduce dose by three quarters, i.e. starting dose should be 10mg daily, and total daily dose should not exceed 25mg daily)

Renal insufficiency:No adjustment is necessary but be aware that atomoxetine may exacerbate hypertension in patients with end stage renal disease.Known CYP2D6 poor metaboliser genotype: Due to several-fold increase in atomoxetine exposure, consider a lower starting dose and slower up-titration. |
| **6. Pharmaceutical aspects** [Back to top](#Responsibilities) |
| Route of administration: | Oral  |
| Formulation: | Atomoxetine hydrochloride hard capsules: 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 mgAtomoxetine hydrochloride 4 mg/mL oral solution |
| Administration details: | Atomoxetine can be taken with or without food.Capsules should not be opened for administration: risk of irritation. Oral solution should not be mixed with food or water; it can prevent the full dose being administered and can negatively affect the taste.If a dose is missed then take it as soon as possible, but no later than the early evening. Do not take more than the usual total daily dose in any 24-hour period. A double dose should not be taken to make up for a missed dose.  |
| Other important information: | The initiating specialist will decide the formulation on an individual basis as this will depend on the needs and preferences of the patient. The oral solution is reserved for those with swallowing difficulties. |
| **7. Significant medicine interactions** [Back to top](#Responsibilities)The following list is not exhaustive. Please see [BNF](https://bnf.nice.org.uk/drug/ciclosporin.html) or [SPC](https://www.medicines.org.uk/emc/search?q=ciclosporin) for comprehensive information and recommended management. |
| * **MAOIs**: avoid atomoxetine use whilst using MAOIs and for a minimum of 14 days after stopping MAOIs. Increased risk of adverse effects.
* **CYP2D6 inhibitors**: increased atomoxetine exposure. E.g. selective serotonin reuptake inhibitors (SSRIs), quinidine, terbinafine, bupropion, cinacalcet, dacomitinib, and Panobinostat. Slower dose titration and lower final dose may be necessary. Clinical response and tolerability should be re-evaluated if a CYP2D6 inhibitor is started or stopped.
* **Potent inhibitors of other cytochrome P450 isoforms** in patients who are poor CYP2D6 metabolisers. It is not clear whether there is a clinically significant increase in atomoxetine exposure in this patient group.
* **Beta-2 agonists, including salbutamol**: high dose beta-2 agonists, such as salbutamol, may potentiate cardiovascular effects.
* **Drugs which prolong the QT interval**: risk of QT interval prolongation. E.g. antipsychotics, class IA and III anti arrhythmic, some antibiotics such as ciprofloxacin or erythromycin, methadone, mefloquine, tricyclic, antidepressants, lithium, and some selective serotonin reuptake inhibitors (SSRIs) such as citalopram and escitalopram.
* **Drugs which cause electrolyte imbalance:** risk of QT interval prolongation. E.g. thiazide diuretics.
* **Drugs which lower the seizure threshold:** risk of seizures. E.g.tricyclic antidepressants, SSRIs, antipsychotics, phenothiazines, mefloquine, chloroquine, bupropion, and tramadol. Use caution when stopping medications that may induce seizures on withdrawal, such as benzodiazepines.
* **Anti-hypertensive drugs:** effectiveness of anti-hypertensives may be decreased, monitoring is required.
* **Drugs that increase blood pressure:** possible additive effects, monitoring is required.
* **Drugs that affect noradrenaline:** possible additive or synergistic pharmacological effects. E.g. dexamfetamine, Lisdexamfetamine, imipramine, venlafaxine, mirtazapine, pseudoephedrine, phenylephrine
 |
| **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 prescribing and monitoring be transferred to primary care. [Back to top](#Responsibilities) |
| **Baseline investigations:*** A full assessment, as recommended by [NICE guidance for ADHD](https://www.nice.org.uk/guidance/ng87/chapter/Recommendations#medication). This should include a medical history and cardiovascular assessment, taking into account conditions that may be contraindications for atomoxetine, and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required.
* Risk assessment for substance misuse and drug diversion
* Height, weight, and body mass index (BMI)
* Appetite
* Blood pressure (BP) and heart rate
* Electrocardiogram (ECG) and cardiology opinion are recommended 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:*** 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, including development or worsening of tic and movement disorders.
* Assessment of symptom improvement. Discontinue if no improvement is observed after 4-8 weeks.

**Ongoing monitoring:*** Cardiovascular monitoring – Blood pressure, pulse recorded after each dose adjustment and at least every 6 months
* Re-evaluation of the need for continued therapy beyond 1 year should be performed, particularly when the patient has reached a stable and satisfactory response. Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on 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. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 9](file:///C%3A%5CUsers%5CEsther-Njane%5CDownloads%5CB1621_ii_atomoxetine-for-patients-within-adult-services.docx#Nine_primary_care_monitoring) remains appropriate.
 |
| **9. Ongoing monitoring (ADHD)*** Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This in southwest London will be carried out by secondary care specialists, 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 changes.

[Back to top](#Responsibilities)See [section 10](#Ten_ADRs_and_Management) for further guidance on management of adverse effects/responding to monitoring results. |
| **Monitoring** | **Frequency** |
| * Children on treatment who are under weight
 | **3 monthly** |
| * Weight for children over 10 years
 | Weight at **3 and 6 months** after starting treatment and every 6 months thereafter |
| * 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
 | **6 monthly** |
| * Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD
 | **Annually** |
| * Assessment of adherence, and for any indication of atomoxetine abuse, misuse, or diversion
 | As required, based on the patient’s needs and individual circumstances |
| Height and weight should be plotted on a growth chart which are available through the RCPCH website <https://www.rcpch.ac.uk/resources/growth-charts> |
| **10. Adverse effects and other management** [Back to top](#Responsibilities)**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. <https://www.medicines.org.uk/emc> |
| **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 |
| Hypertension  | Manage as per local pathways, taking into account risk of clinically significant interactions with several types of antihypertensive medication (see section 7). If blood pressure is significantly raised (see guidance box immediately above), reduce dose of atomoxetine by half and discuss with specialist for further advice. |
| **Gastrointestinal disorders**Including abdominal pain, vomiting, nausea, constipation, dyspepsia | Review and provide advice on dosing; patients may benefit from taking atomoxetine in two equally divided doses (once in the morning, and once in the late afternoon or early evening). Generally, resolves. |
| **Weight or BMI outside healthy range**, including anorexia or weight loss | Recommend small, frequent meals and/or snacks, and high calorie foods of good nutritional value. Recommend taking atomoxetine with or after meals, and not before. Obtain dietary advice if required. Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medicine may be required. |
| **Psychiatric disorders** New or worsening psychiatric symptoms, e.g. suicide related behaviour, psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette’s syndrome), anxiety, agitation or tension, bipolar disorder, or depression | Contact specialist team and refer for psychiatric assessment if appropriate. Refer for urgent psychiatric assessment if suicide related behaviour or ideation occurs. Discuss ongoing benefit of treatment with specialist team |
| **Hepatic effects** Signs or symptoms of liver injury, e.g., abdominal pain, unexplained nausea, malaise, jaundice, or darkening of urine | Perform liver function tests (LFTs), including serum bilirubin, and discuss with specialist team. Discontinue atomoxetine permanently in patients who develop jaundice or for whom there is laboratory evidence of liver injury (if unclear if injury or transient derangement, discuss urgently with specialist). |
| **Nervous system disorders** Somnolence or sedation | Review and provide advice on dosing; patients may benefit from taking atomoxetine in two equally divided doses (once in the morning, and once in late afternoon or early evening). Generally, resolves. |
| New onset of seizures, or increased seizure frequency | Discuss with specialist team. Discontinuation of atomoxetine should be considered |
| **11. Advice to patients and carers** [Back to top](#Responsibilities)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:** * Symptoms of allergic or anaphylactic reactions (e.g., rash, angioedema, or urticaria).
* Sudden acute, painful eye(s), impaired vision, red eye(s), and/or semi-dilated and fixed pupil; risk of **angle closure glaucoma**, seek immediate medical attention, ideally from an eye casualty unit or A&E
* Symptoms suggestive of cardiac disease (e.g., palpitations, exertional chest pain, unexplained syncope, or dyspnoea).
* New or worsening psychiatric symptoms (e.g., psychotic symptoms, aggressive or hostile behaviour, emotional lability, suicide-related behaviour (suicide attempts or suicidal ideation), motor or verbal tics, anxiety, depressive symptoms, or mania).
* **Report suicidal thoughts or behaviour**, and development or worsening of irritability, agitation, and depression.
* New or worsening neurological symptoms (e.g., severe headache, numbness, weakness, paralysis, seizures, or impairment of coordination, vision, speech, language, or memory).
* Risk of **hepatic injury:** report unexplained nausea, malaise, jaundice, or darkening of urine, and new onset severe or persistent abdominal pain.
* If they suspect they may be pregnant or are planning a pregnancy.
* Abnormally sustained or frequent and painful erections. If an erection persists for more than 2 hours go to A&E; this is an emergency.

**The patient should be advised:*** Atomoxetine is subject to drug driving laws. Not to drive, cycle or operate machines if atomoxetine affects their ability to do so safely, e.g., by causing fatigue, somnolence, and dizziness and to inform the DVLA if their ability to drive safely is affected. See <https://www.gov.uk/adhd-and-driving> and [section 11](#Eleven_advice_to_patients).
* Not to stop taking atomoxetine without talking to their doctor and not to share their medicines with anyone else.

**Patient and carer information:*** [» Attention Deficit Hyperactivity Disorder (choiceandmedication.org)](https://www.choiceandmedication.org/swlstg-tr/condition/attention-deficit-hyperactivity-disorder/)
* [ADHD and Mental Health | Signs and Symptoms of ADHD | YoungMinds](https://www.youngminds.org.uk/young-person/mental-health-conditions/adhd-and-mental-health/)
* NHS – attention deficit hyperactivity disorder. <https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd>
* [Atomoxetine for ADHD – Medicines For Children](https://www.medicinesforchildren.org.uk/medicines/atomoxetine-for-adhd/)
* ADHD support groups [Support Groups | The UK ADHD Partnership](https://www.ukadhd.com/support-groups.htm)
* [Patient leaflets | BMJ Best Practice](https://bestpractice.bmj.com/patient-leaflets)
* [ADHD and hyperkinetic disorder for parents | Royal College of Psychiatrists (rcpsych.ac.uk)](https://www.rcpsych.ac.uk/mental-health/parents-and-young-people/information-for-parents-and-carers/ADHD-and-hyperkinetic-disorder-information-for-parents)

Patient information leaflets are also available from [Atomoxetine 10 mg hard capsules - Patient Information Leaflet (PIL) - (emc) (medicines.org.uk)](https://www.medicines.org.uk/emc/product/10507/pil)**ADHD resources for children and young people, parents/carers and primary care professionals** Working with the ADHD Foundation, we have launched new set of booklets for children, teenagers and their parents and carers. There are three separate booklets, each of which has a different focus:• The children’s booklet is an interactive guide with 20 fun activities for children to help them focus, manage their emotions, and succeed• The teenager’s booklet is a guide and workbook with information and activities to support teenagers living with ADHD• The parents/carers booklet is an information and resource guide for parents and carers of children and young people with ADHD and may also be useful for health professionals including those working in primary care.All three booklets are available to share and download on the website: <https://www.transformationpartnersinhealthandcare.nhs.uk/cyp-adhd-resources> |
| **12. Pregnancy, paternal exposure and breast feeding** [Back to top](#Responsibilities)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:**Atomoxetine is not recommended for use during pregnancy unless a clinical decision is made that the potential benefit outweighs the risk to the foetus. Evidence on exposure to atomoxetine during pregnancy is too limited to draw firm conclusions on adverse outcomes. Clinicians should be aware that patients may have other risk factors which independently alter the risks, and additional monitoring should be considered on a case-by-case basis.Patients who become pregnant while taking atomoxetine, or who plan a pregnancy, should be referred to the specialist team for review.Information for healthcare professionals: <https://www.sps.nhs.uk/medicines/atomoxetine/>Information for patients and carers: [USE OF ATOMOXETINE IN PREGNANCY (medicinesinpregnancy.org)](https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-ATOMOXETINE-IN-PREGNANCY/)**Breastfeeding:****T**here is no published evidence on the safety of atomoxetine in breastfeeding. Decisions to use atomoxetine while breastfeeding should be made on a case-by-case basis, taking into account the risks to the infant and the benefits of therapy. Long half-life in slow metabolisers increases risk of accumulation in some breastfed infants. Infants should be monitored for symptoms of CNS stimulation (e.g., decreased appetite or slow weight gain, sleep disturbances, gastrointestinal symptoms), although these may be difficult to detect.Information for healthcare professionals: <https://www.sps.nhs.uk/medicines/atomoxetine/>**Paternal exposure**:No evidence regarding adverse outcomes following paternal exposure was identified. |
| **13. Specialist contact information** [Back to top](#Responsibilities) |
| Name: *[insert name]* Role and specialty: *[insert role and specialty]* Daytime telephone number: *[insert daytime telephone number]* Email address: *[insert email address]* Alternative contact: *[insert contact information, e.g. for clinic or specialist nurse]* Out of hours contact details: *[insert contact information, e.g. for duty doctor]* |
| **14. Additional information** [Back to top](#Responsibilities) |
| 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** [Back to top](#Responsibilities) |
| * eBNFc. Atomoxetine. Accessed via [Atomoxetine | Drugs | BNFC | NICE](https://bnfc.nice.org.uk/drugs/atomoxetine/#indications-and-dose) on 22/11/22.
* Atomoxetine 10 mg hard capsules. Last updated on 02/03/2020. Accessed via [Atomoxetine 10 mg Hard Capsules - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)](https://www.medicines.org.uk/emc/product/11121/smpc) 22/11/22
* NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via [Overview | attention deficit hyperactivity disorder: diagnosis and management | Guidance | NICE](https://www.nice.org.uk/guidance/ng87) on 22/11/22.
* NICE NG43: Transition from children to adults’ services for young people using health or social care services. Last updated February 2016. Accessed via [Overview | Transition from children’s to adults’ services for young people using health or social care services | Guidance | NICE](https://www.nice.org.uk/guidance/ng43) on 22/11/22
* UKTIS. Use of atomoxetine in pregnancy. Last updated December 2017. Accessed via [Atomoxetine in pregnancy (toxbase.org)](https://www.toxbase.org/Poisons-Index-A-Z/A-Products/Atomoxetine-in-pregnancy/) on 22/11/2022.
* Specialist Pharmacy Service. Safety in Lactation: Drugs for ADHD. Last updated October 2020. Accessed via [Safety in Lactation: Drugs for ADHD – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/) on 22/11/2022
* NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: Atomoxetine. Last updated October 2022. Accessed via [Atomoxetine | Prescribing information | Attention deficit hyperactivity disorder | CKS | NICE](https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/atomoxetine/) on 22/11/2022
* MHRA. Drug Safety Update: Atomoxetine (Strattera): increases in blood pressure and heart rate. January 2021. Accessed via Atomoxetine (Strattera): increases in blood pressure and heart rate - GOV.UK (www.gov.uk) on 22/11/2022 .
* MHRA. Drug Safety Update: Atomoxetine (Strattera):Psychotic and manic symptoms in children and adolescents. January 2021. Accessed via [Atomoxetine: risk of psychotic or manic symptoms in children and adolescents - GOV.UK (www.gov.uk)](https://www.gov.uk/drug-safety-update/atomoxetine-risk-of-psychotic-or-manic-symptoms-in-children-and-adolescents) on 22/11/2022
 |
| **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 policy – 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** [Back to top](#Responsibilities)Define the referral procedure from hospital to primary care prescriber & route of return should the patient’s condition change. |
| Shared care from hospital to primary carePrimary care to hospital – Urgent referrals mental health crisis line or A&E out of hours. For routine/non-urgent referrals contact local CAMHs team. |
| **18. Communication**Please note that the clinical letter received from the specialist team should have the relevant contact details. If this is not provided you may find the following contact details useful.**Medicines Information Services*** South West London and St Georges Mental Health Hospital: Tel. 020 3513 6829
* South London and Maudsley (SLAM): Tel. 020 3228 2317
* Georges Hospital medicines helpline: Tel. 020 872 51033
* Kingston Hospital medicines helpline: Tel. 020 85467711 ext.2092
* Epsom and St Helier Trust medicines helpline: Tel.020 872 51033
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