Shropshire Community Health NHS Trust

NHS Telford and Wrekin Clinical Commissioning Group

Atomoxetine
Effective Shared Care Agreement
For Attention Deficit Hyperactivity Disorder (ADHD)

Section 1: Shared Care arrangements and responsibilities

Section 1.1 Agreement to transfer of prescribing of Atomoxetine to GP

Patient details

Name: _____

Address: _____

Date of Birth: _____

NHS number: _____

Contact details
Consultant:
Address:

Email:

Contact number:

GP

Address:

Email:

Contact number:

Patient

Name:

Contact number:

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

Consultant Signature: _____

Date: _____

GP Signature: _____

Date: _____

Patient Signature: _____

Date: _____

Section 1.2: Shared Care responsibilities

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
1. Discuss with the patient options for treatment and the suitability of atomoxetine
2. Discuss the potential benefits and side effects of treatment with the patient:
3. Initiate atomoxetine treatment.
4. 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. .
5. Undertake baseline tests-height, weight and cardiovascular status including heart rate & blood pressure.
6. Commence treatment with atomoxetine and once patient is on a stable dose between visits, consider transfer of prescribing and monitoring to GP. .
7. Ensure agreed signed shared care form has been received back from GP to indicate that the GP is in agreement with prescribing and monitoring.
8. Ensure this has been discussed with patient, and that patient has signed SCA form
9. Regular follow-up of patient (at least annually)
10. Communicate promptly with the GP when treatment is changed
11. Advise GP on dosage adjustment and when and how to stop treatment
12. Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition and ensure that clear backup arrangements exist for GPs to obtain advice and support
13. Report adverse events to the MHRA (via Yellow Card)

Responsibilities of the General Practitioner
1. Reply to the request for shared care as soon as practicable, and if required discuss shared care arrangements with patient.
2. Prescribe Atomoxetine at recommended dose
3. Arrange and record on-going monitoring as agreed with specialist:
4. Ensure no drug interactions with other medicines
5. Check patient is using adequate contraception
6. Continued prescribing is appropriate for patients attending regular review
7. Report adverse events to the MHRA (via Yellow Card)

Responsibilities of the patient
1. To take the prescribed medication regularly unless advised by GP or specialist
2. To attend scheduled appointments with consultant and GP and for monitoring as detailed above
3. Report any adverse effects to the consultant or GP.
4. Share any concerns in relation to treatment.
6. Report to the consultant or GP if they do not have a clear understanding of the treatment

Section 2: General Information on Atomoxetine

Licensed Indication

Atomoxetine is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older and in adolescents as part of a comprehensive treatment programme. Treatment must be initiated by a specialist in the treatment of ADHD. Diagnosis should be made according to DSM-IV criteria or the guidelines in ICD-10

Dosage and administration

The Summary of Product Characteristics (SPC) states that treatment must be initiated by or under the supervision of a physician with appropriate knowledge and experience of childhood behavioural disorders.

Atomoxetine is available as capsules to be taken orally. It is normally given as a single dose in the morning. Patients who suffer from side effects may benefit from dividing the dose, which should then be taken in the morning and late afternoon or early evening.

In children and adolescents under 70 kg body weight, atomoxetine should be initiated at a total daily dose of 0.5 mg/kg, maintained for at least seven days. The dose should then be titrated upwards according to response and tolerability to the recommended maintenance dose of 1.2 mg/kg/day.

In children and adolescents over 70 kg body weight and adults the initiation and recommended maintenance doses are 40 and 80 mg daily, respectively.

In patients with moderate and severe hepatic insufficiency doses should be reduced to 50% and 25% of the standard dose, respectively. No adjustments are required for those with renal insufficiency

Contraindications

Atomoxetine should not be used in combination with monoamine oxidase inhibitors (MAOIs), or within two weeks after discontinuing therapy with a MAOI. Treatment with a MAOI should not be initiated within two weeks after discontinuing atomoxetine.

Atomoxetine should not be used in patients with narrow-angle glaucoma, as in clinical trials the use of atomoxetine was associated with an increased incidence of mydriasis.

Seizures are a potential risk with atomoxetine and therefore it should be introduced with caution in patients with a history of seizure. Discontinuation of atomoxetine should be considered in any patient developing seizure or if there is an increase in seizure frequency.

Reports of QT interval prolongation have been received in association with atomoxetine. Therefore, it should be used with caution in those with congenital or acquired long QT or a family history of QT prolongation. This risk may be increased if atomoxetine is used concomitantly with other drugs that produce QT prolongation, drugs that can cause electrolyte disturbances and those that inhibit cytochrome P450 2D6.

Due to concerns about an increased risk of suicidal thoughts and behaviour, patients should be monitored for signs of depression, suicidal thoughts or suicidal behaviour and referred for appropriate treatment if necessary.

There is a risk of rare, but sometimes severe, hepatic disorders. atomoxetine should be discontinued in patients with jaundice or laboratory evidence of liver injury, and should not be restarted.

Atomoxetine causes clinically important increases in blood pressure or heart rate, or both, in a small proportion of patients. Atomoxetine should not be used in patients with severe cardiovascular or cerebrovascular disorders. Thorough pretreatment screening and regular monitoring of cardiovascular status is recommended. Specialist cardiac evaluation and advice should be sought if pretreatment findings suggest cardiac disease or history, or if symptoms suggesting cardiac disease are found during treatment[1]

Side effects

The most commonly reported adverse events in clinical trials were headache, rhinitis, abdominal pain, pharyngitis, anorexia, vomiting, cough, somnolence and insomnia.

Small increases in blood pressure, both diastolic and systolic (about 2 to 3 mm), and pulse rates (about 6 to 9 bpm) were seen in the groups taking atomoxetine. Significant decreases in weight (of about 0.5 to 1.0 kg) were reported with atomoxetine in most studies.

The MHRA has advised that atomoxetine at normal doses, can be associated with treatment-emergent psychotic or manic symptoms (e.g., hallucinations, delusional thinking, mania, or agitation) in children and adolescents without a history of psychotic illness or mania. If such symptoms occur, consideration should be given to a possible causal role of atomoxetine and discontinuation of treatment[2]

It remains possible that atomoxetine might exacerbate pre-existing psychotic or manic symptoms

Sudden death has been reported in children and adolescents with structural cardiac abnormalities who were taking atomoxetine at usual doses. Although some serious structural cardiac abnormalities alone carry an increased risk of sudden death, atomoxetine should only be used with caution in children or adolescents with known serious structural cardiac abnormalities and in consultation with a cardiac specialist.

Drug Interactions[3]

Analgesics – increased risk of ventricular arrhythmias with **methadone** and increased risk of convulsions with **tramadol.**

Antidepressants – metabolism of atomoxetine possibly inhibited by **fluoxetine** and **paroxetine**, increased risk of ventricular arrhythmias with **tricyclics.**

Bupropion – possible increased risk of convulsions.

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.

Monitoring

The patient's blood pressure, heart rate and growth parameters should be monitored, especially in the early stages of treatment.

[1] MHRA Drug Safety Update Vol 5 Issue 6 January 2012
[2] MHRA Drug Safety Update Vol 2 Issue 8 March 2008
[3] BNF 65 March- September 2013