TAYSIDE PROTOCOL FOR PRESCRIBING ATOMOXETINE (STRATTERA®)

Licensed indications:

Strattera 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.

Scottish Medicines Consortium advice:

Atomoxetine (Strattera®) is accepted for restricted use within NHS Scotland for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older or in adolescents. It is restricted to use in patients who do not respond to stimulants or in whom stimulants are contraindicated or not tolerated. It is restricted to use by physicians with appropriate knowledge and expertise in treating ADHD. This advice concerns use in children and adolescents only and does not cover use in adults. Atomoxetine (Strattera®) is not a Controlled Drug under the Misuse of Drugs Regulations 2001.

Medicines Advisory Group advice:

- Atomoxetine is recommended locally for the treatment of ADHD in the following groups of children/adolescents:
  - those who have not responded to stimulant medication
  - those who have been unable to tolerate stimulant medication (eg due to decreased appetite, growth problems, sleep disturbance, depressed mood or mood lability or exacerbation of comorbid tics)
  - those in whom stimulant medication is contraindicated (such as those with co-morbid chronic motor tics or Tourette's syndrome)

  Treatment should be under the direction of a specialist in childhood behavioural disorders.
  The first three months of treatment should be prescribed by the Child & Adolescent Mental Health Service (CAMHS).

Prescriber details:

Prescription for the first three months of treatment should be from CAMHS thereafter by the patient's general practitioner in accordance with the local ADHD shared care protocol**.**

Criteria for patient selection:

Treatment should be considered in the groups of patients described above:
(The SPC states that in adolescents whose symptoms persist into adulthood and who have shown clear benefit from treatment, it may be appropriate to continue treatment into adulthood. However, start of treatment in adults is not appropriate.)

Administration details:

Atomoxetine can be administered as a single daily dose in the morning, with or without food. Patients who do not achieve a satisfactory clinical response or have significant adverse effects when taking atomoxetine as a single daily dose might benefit from taking it twice daily as evenly divided dose in the morning and late afternoon or evening.
Refer to SPC for dose titration details according to body weight.
No distinct withdrawal symptoms have been described. In patients where there are significant adverse effects, atomoxetine may be stopped abruptly; otherwise atomoxetine may be discontinued by tapering off over a suitable period of time.
Patients and families should be advised that clinical improvement in symptoms will take up to 2-6 weeks to become apparent and may take longer.

Contra-indications:

Atomoxetine should not be used in combination with monoamine oxidase inhibitors (MAOIs).
Atomoxetine should not be used within a minimum of 2 weeks after discontinuing therapy with a MAOI.
Treatment with a MAOI should not be initiated within 2 weeks after discontinuing atomoxetine.
Patients with narrow angle glaucoma, as trials have indicated use of atomoxetine was associated with an increased incidence of mydriasis.

Interactions:

Atomoxetine should not be used with MAOIs (see above).
Atomoxetine should be administered with caution to patients being treated with high dose nebulised or systemically administered salbutamol or other $beta_2$ agonists.
Use atomoxetine with caution with pressor agents.
Drugs that affect noradrenaline including antidepressants such as impramine, venlafaxine and mirtazipine, or the decongestants pseudoephedrine or phenylephrine, should be used cautiously when co-administered with atomoxetine because of the potential for additive or synergistic pharmacological effects.
CYP2D6 inhibitors (eg fluoxetine, paroxetine) slower titration of atomoxetine may be necessary if co-administered.
Atomoxetine does not cause clinically significant inhibition or induction of cytochrome P450 enzymes.

Side-effects/cautions:

Common >10% patients: abdominal pain, nausea, decreased appetite, dry mouth
Less common 1-10% patients: anorexia, weight decrease, dyspepsia, constipation, dizziness, somnolence, cold/flu symptoms, early morning wakening, irritability, mood swings, mydriasis, dermatitis, rash, pruritis.
Other effects: several reports of hepatic disorders have been noted in patients treated with atomoxetine. Many of these cases have been found to have other risk factors. The risk is estimated at below 1 in 50,000 patients treated. Patients and their parents/carers should be made aware of these risks and of potential signs and symptoms of hepatic disorder.
In paediatric trials patients taking atomoxetine experienced a increase in heart rate of about 6 beats/minute and mean increase in systolic and diastolic blood pressure of about 2 mmHg compared with placebo, none of these effects have been found to be clinically significant.
Atomoxetine should be used with caution in patients with hypertension, tachycardia, or cardiovascular or cerebrovascular disease.
In patients with pre-existing renal or hepatic disease, initial and target dose should be reduced.

Monitoring - response to treatment:

Clinical response should be monitored by physicians with appropriate knowledge and expertise in treating ADHD. In Tayside this remit falls to CAMHS. Contact details as follows:

Dundee: Centre for Child Health, 19 Dudhope Terrace, tel: 01382 204004
Perth: Child & Family Psychiatry, Pitcullen House, Murray Royal Hospital, tel: 01738 621151

Monitoring response to treatment should include the use of standardised rating scales completed by clinician, parents/carers and teachers.
Periodic assessment of the need for ongoing treatment during long-term treatment will also be made by the CAMHS professionals.

Monitoring – treatment safety:

Growth rates (height and weight) together with blood pressure and pulse should be routinely monitoring throughout treatment, at least twice yearly following treatment stabilisation, by CAMHS professionals unless alternative arrangements have been agreed with an individuals general practitioner.
There is no requirement for a pre-treatment ECG or baseline blood testing to be performed. There is no requirement for such measures to be routinely performed during treatment with atomoxetine unless indicated by clinical presentation.

Written by: Dr Sarah Seth **Date: 4th July 2005**

Approved by: Dr David Coghill **Date: 6th July 2005**

Reviewed by: The Developmental Psychiatry Team **Date: 8th Jan 2007**

Review date: January 2009