Physician's guide for assessing and monitoring cardiovascular risk when prescribing Strattera

Strattera 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.

Diagnosis should be made according to current DSM criteria or the guidelines in ICD. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or psychiatrist.

In adults, the presence of symptoms of ADHD that were pre-existing in childhood should be confirmed. Third-party corroboration is desirable and Strattera should not be initiated when the verification of childhood ADHD symptoms is uncertain. Diagnosis cannot be made solely on the presence of one or more symptoms of ADHD. Based on clinical judgment, patients should have ADHD of at least moderate severity as indicated by at least moderate functional impairment in 2 or more settings (for example, social, academic, and/or occupational functioning), affecting several aspects of an individual's life.

A comprehensive treatment programme typically includes psychological, educational and social measures and is aimed at stabilizing patients with a behavioural syndrome characterized by symptoms which may include chronic history of short attention span, distractibility, emotional lability, impulsivity, moderate to severe hyperactivity, minor neurological signs and abnormal EEG. Learning may or may not be impaired.

Pharmacological treatment is not indicated in all patients with this syndrome and the decision to use the drug must be based on a very thorough assessment of the severity of the patient's symptoms and impairment in relation to the patient's age and the persistence of symptoms.

Full information on the safety and efficacy of Strattera is provided in the Summary of Product Characteristics (See www.medicines.org.uk/emc *[or other local website]*).

This guide provides specific information for prescribing physicians in regard to prescreening and ongoing monitoring of cardiovascular safety.

Physicians should be aware that Strattera can affect heart rate and blood pressure. Patients who are being considered for treatment with Strattera should have a careful history (including assessment of concomitant medications, past and present co-morbid medical disorders or symptoms as well as any family history of sudden cardiac or unexplained death or malignant arrhythmia) and physical exam to assess for the presence of cardiac disease. Patients should be referred for further specialist cardiac evaluation if initial findings suggest such history or disease.

It is further recommended that cardiovascular status should be regularly monitored with blood pressure and pulse recorded after each adjustment of dose and then at least every 6 months. For paediatric patients the use of a centile chart is recommended. For adults, current reference guidelines for hypertension should be followed.

Atomoxetine should be used cautiously with antihypertensive drugs and with pressor agents or medications that may increase blood pressure (such as salbutamol).

The tools provided in this guide should help appropriate screening and monitoring of patients.

Strattera should be used in accordance with national clinical guidance on treatment of ADHD where available. 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.

Checklist for actions to take before prescribing / dispensing or administering Strattera

Patient's ID_____ Date_____

A specialist in the treatment of ADHD has made the initial diagnosis for your patient according to DSM criteria or guidelines in ICD. ☐

A comprehensive medical history has been performed, including: ☐

- Concomitant medications: _____
_____
Note that atomoxetine should be used cautiously with antihypertensive drugs and with pressor agents or medications that may increase blood pressure, such as salbutamol

- Family history:_____ _____
Note that a family history of sudden cardiac/unexplained death or malignant arrhythmia is a risk factor for cardiovascular outcomes

- Past and present co-morbid medical disorders or symptoms:_____
_____

Physical examination has been performed ☐

Notes:_____

A baseline evaluation of the patient's cardiovascular status has been made, including measurement of blood pressure and heart rate ☐
(For children, it is recommended that these measurements are recorded on a centile chart, if a centile chart is not available, recordings may be made in the attached chart.)

Evaluation shows an absence of severe cardiovascular or cerebrovascular disorder. ☐

- *Some examples of patients who would be expected to experience critical deterioration in their preexisting cardiovascular or cerebrovascular condition would include those with the following conditions: severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias, channelopathies (disorders caused by the dysfunction of ion channels), cerebral aneurysm and stroke.*

check one

Initial findings from the patient's history and physical examination do not suggest any cardiovascular or cerebrovascular disease ☐

OR

Initial findings from the patient's history and physical examination suggest a cardiovascular or cerebrovascular disease and a cardiac specialist has advised that treatment with Strattera may be initiated under careful monitoring. ☐

All boxes should be checked before you proceed further to start treatment in your patient

Checklist for monitoring to manage cardiovascular risks with Strattera treatment

Patient's ID_____ Date_____

If it has been 6 months since your patient's last assessment or if you have adjusted their dose, blood pressure and heart rate have been measured and recorded ☐

(For children, it is recommended that these measurements are recorded on a centile chart, if a centile chart is not available, recordings may be made in the attached chart.)

Notes:_____

check one

Your patient has NOT developed signs/symptoms of new cardiovascular disorder or worsening of a pre-existing cardiovascular disorder ☐

OR

Your patient has developed signs/symptoms of new cardiovascular disorder or worsening of a pre-existing cardiovascular disorder and after further investigation a cardiac specialist has advised that treatment with Strattera may be continued ☐

Notes_____

check one

Your patient has NOT developed new neurologic signs/symptoms ☐

OR

Your patient has developed new neurologic signs/symptoms and specialist has advised that treatment with Strattera may be continued ☐

Notes_____

check one

Your patient has been on treatment with atomoxetine for less than 1 year ☐

OR

Your patient has been on treatment with atomoxetine for more than 1 year, and a re-evaluation of the need for therapy by a specialist in the treatment of ADHD has been conducted ☐

Note_____

A check should be made in each box at every visit during treatment

Measurements recording chart

Patient's ID_____

Date	**Reason for recording** (pretreatment record, 6 month interval, dose adjustment, etc.)	**Blood Pressure**		**Heart Rate**		**Actions taken** (continue/discontinue treatment, increase/decrease dose, consult cardiac specialist, etc.)
		SBP / DBP (mm Hg)	**SBP / DBP within normal range?** (Y/N)	**HR or Pulse** (bpm)	**HR within normal range?** (Y/N)	