IRISH MEDICINES BOARD

Notice Information: - 3rd Party Publications 05 March 2009

Part 1. Product Information

a)	Title:	Medicines for the Management of ADHD (I) Atomoxetine (Strattera) - MIMS Publication
b)	Product Name/Type:	Atomoxetine (Strattera)
c)	Reference:	MIMS Publication

Part 2. Problem/Issue

a) Problem/Issue:

Atomoxetine is authorised 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 with atomoxetine must be initiated by, or under the supervision of, a physician with appropriate knowledge and experience in treating ADHD. A comprehensive treatment programme typically includes psychological, educational and social measures and is aimed at stabilising children with a behavioural syndrome characterised by symptoms which may include chronic history of short attention span, distractability, 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 children with this syndrome and the decision to use the drug must be based on a very thorough assessment of the severity of the child's symptoms in relation to the child's age and the persistence of symptoms.

In light of concern about the increased risk of suicidal thoughts and behaviour associated with its use, a European review of available data on the risks and benefits of atomoxetine was undertaken. This review concluded that the overall balance of risks and benefits of atomoxetine remains positive in the treatment of ADHD in children of 6 years and older and in adolescents. However, in order to optimise the safe use of atomoxetine, the IMB wishes to highlight the following safety information to healthcare professionals:

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.

Seizures are a potential risk with atomoxetine and it should therefore 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. Caution is advised with concomitant use of medicines which are known to lower the seizure threshold (such as antidepressants, neuroleptics, mefloquine, buproprion or tramadol).

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 (such as

neuroleptics, class IA and III anti arrhythmics, moxifloxacin, erythromycin, methadone, mefloquine, tricyclic antidepressants or lithium), drugs that can cause electrolyte disturbances (such as thiazide diuretics) and those that inhibit cytochrome P450 2D6.

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.

Healthcare professionals are reminded to adhere to the approved recommendations for use of atomoxetine and to closely monitor patients during use, advising them to report any symptoms associated with treatment to their doctor. To date, adverse reactions reported in Ireland have been consistent with the known safety profile of the product and healthcare professionals are encouraged to continue reporting suspected cases to the IMB in the usual way. Online reporting is available by following the links at www.imb.ie.

Part 3. Keywords

a) Keywords: Atomoxetine Strattera ADHD Adverse reaction