IRISH MEDICINES BOARD

Notice Information: Human Medicines - 3rd Party Publications 30 April 2007

Part 1. Product Information

a)	Title:	METHYLPHENIDATE
b)	Product Name/Type:	Ritalin/Ritalin LA;Concerta XL;Equasym;Equasym XL
c)	Active Substance:	Methylphenidate
d)	Reference:	MIMS Publication April 2007

Part 2. Target Audience

a)	Target Audience:	Healthcare Professionals

Part 3. Problem/Issue

a)	Problem/Issue:	Methylphenidate is a CNS stimulant currently authorised in Ireland as part of a comprehensive programme for the treatment of attention-deficit hyperactivity disorder (ADHD), where remedial measures alone are insufficient. Treatment should be under the supervision of a specialist in childhood behavioural disorders and a diagnosis should be made according to DSM-IV criteria or the guidelines in ICD-10. In addition, methylphenidate treatment is not indicated for use in all children with ADHD, and a decision to use it should be based on a thorough assessment of the severity of symptoms. Since 1970, the IMB has received a total of 44 suspected adverse reaction reports associated with use of methylphenidate. These reports include those commonly associated with methylphenidate such as nervousness and insomnia, gastrointestinal disorders and anorexia, as well as those known to occur rarely, i.e. neutropenia, tachycardia, palpitations, arrhythmia and changes in blood pressure. A number of reports of neuropsychiatric adverse reactions such as convulsions, agitation, aggression, and suicidal thoughts/tendency have also been received, as well as several reports of drug abuse/dependence. The safety profile of methylphenidate has been subject to regular review over the past few years, which has resulted in a number of updates to the product information and as such, the IMB wishes to remind healthcare professionals of the following important safety information related to its use: Methylphenidate should not be used in children under 6 years of age, as safety and efficacy in this age group have not been established. Methylphenidate should not be used in patients with marked anxiety, agitation or tension as its use may aggravate these symptoms. Methylphenidate should not be used in patients with a history of, or known drug dependence, alcoholism, anorexia nervosa, aggression, severe depression, suicidal tendencies or psychotic disorders. Clinical experience suggests methylphenidate may exacerbate symptoms of behavioural disturbance and thought disorders in psychotic children. In addition, chronic abuse of methylphenidate can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Methylphenidate should not be used in patients with hyperthyroidism, thyrotoxicosis or glaucoma. Methylphenidate should not be used in patients with a diagnosis or family history of motor tics, or Tourette's syndrome. Methylphenidate should not be used in patients with heart failure or recent myocardial infarction. In addition, it is not recommended for use in patients with severe hypertension, as it increases heart rate and blood pressure. Sudden death has been reported in association with use of CNS stimulants at usual doses in children with structural cardiac abnormalities. Although some structural abnormalities may carry an increased risk of sudden death, CNS stimulants are not recommended for use in children/adolescents with known structural cardiac abnormalities. All patients should be closely monitored throughout treatment with methylphenidate. In particular, blood pressure should be monitored at appropriate intervals in all patients, especially those with hypertension. In addition, patients requiring long term therapy should have platelet and blood counts perf

	performed periodically. Healthcare professionals are reminded that suspected adverse reactions, including those associated with use of methylphenidate, should be reported to the IMB in the usual way.

Part 4. Keywords

a) Keywords:	Methylphenidate