IRISH MEDICINES BOARD

Notice Information: - 3rd Party Publications 23 April 2009

Part 1. Product Information

a)	Title:	Medicines for the Management of Attention Deficit Hyperactivity Disorder (ADHD) (Part II) – Methylphenidate - Apr 09, 2009 - MIMS Publication
b)	Product Name/Type:	Methylphenidate
c)	Reference:	MIMS Publication

Part 2. Problem/Issue

a) Problem/Issue:

Methylphenidate

Part I of this series of articles on Medicines for the Management of Attention Deficit Hyperactivity Disorder (ADHD) focused on atomoxetine. This article provides updated guidance on the safe and effective use of methylphenidate in ADHD.

The European Medicines Agency (EMEA) in conjunction with the IMB has completed a review of the benefits and risks of methylphenidate after recent concerns about its cardiovascular, cerebrovascular, and psychiatric safety and its long-term effects. Following this review of the currently available data, the EMEA's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of methylphenidate continue to outweigh the risks when used in its licensed indication. Methylphenidate is indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years or older and adolescents, who are diagnosed according to DSM-IV criteria or guidelines in ICD-10.

The EU review concluded that new recommendations on prescribing methylphenidate, on pre-treatment screening and ongoing monitoring of patients are needed in order to optimise the safe use of these medicines. The IMB wishes to alert healthcare professionals to the following recommendations for safe use of methylphenidate

Key safety information and advice for healthcare professionals:

Contraindications—methylphenidate should not be used in patients with:

• Diagnosis or history of severe depression, anorexia nervosa or anorexic disorders, suicidal tendencies, psychotic symptoms, mania, schizophrenia, severe mood disorders, or psychopathic or borderline personality disorder

• Diagnosis or history of severe and episodic (type I) bipolar (affective) disorder that is not well-controlled

• Pre-existing cerebrovascular disorders e.g. cerebral aneurysm and vascular abnormalities, including vasculitis or stroke

• Unless specialist cardiac advice has been obtained: in pre-existing cardiovascular disorders, including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant conge

congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias, and dysfunction of cardiac ion channels

Pre-treatment screening

• Before prescribing, the patient's baseline cardiovascular status, including blood pressure and heart rate, should be assessed

• A complete history should be taken, documenting: concomitant medicines; past and present medical and psychiatric disorders or symptoms; family history of sudden cardiac death, unexplained death, or malignant arrhythmia; and accurate pre-treatment height and weight on a growth chart. Patients who are being considered for treatment with methylphenidate should also have physical examination for the presence of heart disease

• Patients should receive further specialist cardiac evaluation if initial findings suggest such history or disease. Caution should be used when treating patients whose underlying medical conditions might be compromised by increased blood pressure or heart rate

Ongoing monitoring

• Blood pressure and pulse should be recorded on a centile chart at every dose adjustment and then at least every 6 months.

• Height, weight, and appetite should be recorded at least every 6 months on a growth chart.

• Methylphenidate could cause or worsen some psychiatric disorders such as depression, suicidal thoughts, hostility, anxiety, agitation, psychosis, and mania. Development of new or worsening of pre-existing, psychiatric symptoms should be monitored at every dose adjustment and then at least every 6 months, and at every visit.

• Prescribers should look out for signs of diversion (transfer of the medicine from the individual for whom it was prescribed to one for whom it is not prescribed), misuse, and abuse of methylphenidate.

• Patients who develop symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea, or other symptoms suggestive of heart disease during methylphenidate treatment should undergo prompt specialist cardiac evaluation.

There is a lack of data on the long-term effects of methylphenidate. Wh

There is a lack of data on the long-term effects of methylphenidate. When patients are prescribed methylphenidate for extended periods (i.e. > 1 year), physicians should periodically interrupt treatment at least once a year to assess whether continuation is necessary. The longer-term safety of methylphenidate remains under close review, and the results of ongoing studies to better characterise the known or potential risks of ADHD medicines will be evaluated when available.

As part of the on-going monitoring of the safety of methylphenidate, healthcare professionals are reminded to adhere to the approved recommendations for use of methylphenidate 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: Methylphenidate