IRISH MEDICINES BOARD

Notice Information: Human Medicines - 3rd Party Publications 01 July 2005

Part 1. Product Information

a)	Title:	CODEINE-CONTAINING ANALGESICS
b)	Product Name/Type:	Codeine-Containing Analgesics - MIMS
c)	Reference:	MIMS Publication July 2005
d)	Prescription Required:	No

Part 2. Problem/Issue

a)	Problem/Issue:	Further to a previous article about codeine-containing medicinal products (March 2004) and recent publicity regarding possible inappropriate use, the Irish Medicines Board wishes to again highlight among healthcare professionals the importance of discussing use of all medications (including non-prescribed medicinal products) with patients/consumers. In addition, patients should be advised about the need to strictly adhere to the recommended dosage and duration of use and to avoid chronic use, which is associated with dependence. Health care professionals are also reminded of the following: Use of codeine is contra-indicated in patients with respiratory depression. Opioid analgesics such as codeine should be given with care to patients receiving tricyclic antidepressants or monamine oxidase inhibitors. The effect of CNS depressants (including alcohol) may be potentiated by codeine. Codeine can produce typical opioid effects including constipation, nausea, vomiting, dizziness, lightheadedness, confusion, drowsiness and urinary retention. The frequency and severity are determined by dosage, duration of treatment and individual sensitivity. Codeine is a narcotic analgesic and no more than the recommended dose should be taken in any 24-hr period. Consumption of quantities in excess of the recommended dose, or for a prolonged period of time, may lead to tolerance, psychological and physical dependence and may result in symptoms such as restlessness and irritability upon cessation of this medicine. Since 1981, the IMB has received a total of eight Adverse Drug Reaction (ADR) reports of dependence associated with use of codeine-containing medicinal products, all of which arose with prolonged use and/or doses exceeding those recommended. The volume of these spontaneous ADR reports and available literature reviews suggest the overall number of reports of misuse is small, compared with the volume of sales of the products. However, recent information has highlighted anecdotal concerns raised from some areas around the country, which appear from the currently available information to have mainly arisen in the context of multiple drug abuse. To ensure a complete and comprehensive overview of the national experience of this issue is available for review and evaluation, the IMB requests healthcare professionals to notify any suspected cases of tolerance/dependence/addiction as soon as possible, in the usual way. This issue is scheduled for consideration by the IMB's Expert Sub-committee of the Advisory Committee for Human Medicines shortly and any further advice/recommendations from the Committee will be issued following this review. A downloadable version of the ADR report form is available from the IMB's website (www.imb.ie). Downloaded forms may be completed and sent by freepost to the IMB. Envelopes should be marked "Freepost", Pharmacovigilance Unit, Irish Medicines Board, T he Earlsfort Centre, Earlsfort Terrace, Dublin 2. Alternatively completed forms may be submitted by fax (01-6762517). Post-paid report cards are also available from the Pharmacovigilance Unit at the IMB (01-6764971).

Part 3. Keywords

a)	Keywords:	CODEINE CONTAINING ANALGESICS