IRISH MEDICINES BOARD

Notice Information: Human Medicines - 3rd Party Publications 01 September 2007

Part 1. Product Information

a)	Title:	PIROXICAM
b)	Product Name/Type:	Feldene and Brexidol
c)	Reference:	MIMS Publication - September 2007
d)	Product Classification:	Non-Steroidal Anti-inflammatory

Part 2. Problem/Issue

a)	Problem/Issue:	Piroxicam is a non-steroidal anti-inflammatory drug [NSAID]. It has been available on the market for many years and has been used in the treatment of many painful conditions. Following a European-wide safety review of piroxicam for systemic use, it has now been agreed that because of the risk of gastrointestinal and cardiovascular side effects as well as serious skin reactions the use of piroxicam should be restricted as follows: Piroxicam should no longer be used for treatment of short-term painful and inflammatory conditions. Piroxicam is now only recommended for use as a second line treatment for the symptomatic relief of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. Prescription of piroxicam should always be initiated by a physician experienced in the treatment of patients with inflammatory or degenerative rheumatic diseases. Treatment with piroxicam should be used in the lowest dose (no more than 20 mg per day) and for the shortest duration possible and treatment should be reviewed after the first 14 days of starting. Prescribers should always consider prescribing piroxicam with a gastro-protective agent, such as misoprostol or a proton-pump inhibitor. Piroxicam should not be prescribed for patients who are more likely to develop side effects, such as those with a history of gastro-intestinal disorders associated with bleeding, or those who have had skin reactions to other medicines. Piroxicam should not be prescribed in association with any other NSAID or an anticoagulant. The IMB is currently working with the companies marketing medicines containing piroxicam in Ireland to ensure that the product information is appropriately updated to reflect this important safety information. Healthcare professionals are reminded that suspected adverse reactions, including those associated with use of piroxicam, should be reported to the IMB in the usual way. A downloadable and on-line 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 Section, Irish Medicines Board, The 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:	FELDENE BREXIDOL Piroxicam