

Notice Information: - 3rd Party Publications 14 June 2013

Part 1. Product Information

a) Title: PRAC recommends the same cardiovascular precautions for diclofenac as for selective COX-2 inhibitors

b) Product Name/Type: Systemic Diclofenac-containing medicines

Part 2. Problem/Issue

a) Problem/Issue: The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) has concluded that the effects of the painkiller diclofenac on the heart and circulation when given systemically (by means such as capsules, tablets or injections) are similar to those of selective COX-2 inhibitors, another group of painkillers. This applies particularly when diclofenac is used at a high dose (150 mg daily) and for long-term treatment. The PRAC concluded that the benefits of diclofenac still outweigh the risks but recommended that the precautions already in place to minimise the risks of arterial thromboembolic events (blood clots in the arteries) with selective COX-2 inhibitors should also be applied to diclofenac.

The safety of NSAIDs has been closely monitored by regulatory authorities in the European Union. Reviews of these medicines carried out in 2005, 2006 and 2012 have confirmed that NSAIDs as a class are associated with a small increased risk of arterial thromboembolic events, which in some cases has led to heart attack or stroke, particularly if used at high dose and for long-term treatment. The product information for all NSAIDs warns of this risk, and recommends that NSAIDs be used at the lowest effective dose for the shortest period of time necessary to control symptoms.

The PRAC recommendation will be considered by the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) at its meeting on 24-26 June 2013.

Healthcare professionals will receive a letter with detailed information on the outcome of this review.

Patients who have any questions should speak to their doctor or pharmacist.

Part 3. Enquiries

- a) All enquiries should be made to:

For full EMA statement please refer to link below:

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