Start of review of Ibuprofen medicines when taken in high doses over long periods

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Information on Ibuprofen

- Ibuprofen is one of the most widely used medicines for pain and inflammation and has a well-known safety profile, particularly at usual doses.
- It works by blocking an enzyme called cyclo-oxygenase, which produces prostaglandins, substances that are involved in inflammation and pain.
- The usual dose for adults and children over 12 years of age is 200 to 400 mg, 3 or 4 times a day as needed. It is also used in children under 12 in a low dose syrup form.
- Ibuprofen is present in medicines as a mixture of two molecules that are enantiomers (mirror images of each other). Dexibuprofen, the active enantiomer, is sometimes available on its own and is therefore included in this review. No products containing only dexibuprofen are authorised for use in Malta.
- Ibuprofen and dexibuprofen are currently available in a number of different formulations. Most formulations covered by the current review are for systemic use (such as those taken by mouth or injection but not topical medicines like creams and gels).

Information from European Medicines Agency about the safety concern

The EMA's Pharmacovigilance and Risk Assessment Committee (PRAC) has started a review to evaluate the cardiovascular risks with high doses of systemic ibuprofen medicines (2,400 mg per day) taken regularly for long periods.

Ibuprofen is usually taken at lower doses and for short periods of time and there is no suggestion of a similar cardiovascular risk with ibuprofen as used by the overwhelming majority of patients.

Ibuprofen belongs to a class of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). The safety of these medicines including their cardiovascular risks has been under close review by the EMA and national regulatory authorities for many years. The results of a published analysis of clinical trial data, have suggested that the cardiovascular risk with

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt

diclofenac and high-dose ibuprofen (2,400 mg) may be similar to the known risk with COX-2 inhibitors (also of the NSAID class).[1]

The PRAC will also evaluate evidence on the interaction of ibuprofen with low-dose aspirin (taken to reduce the risk of heart attacks and strokes) to decide whether current advice to healthcare professionals is sufficient.

While the review is ongoing, patients should continue to use their medicines as per the instructions in the package leaflets or as directed by their doctor or pharmacist.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on ibuprofen. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority yellow card scheme or online at **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Prof. John J Borg PhD (Bristol)
Post-licensing Director

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

[1] Vascular and upper gastrointestinal effects of non-steroidal anti-inflammatory drugs: meta-analyses of individual participant data from randomised trials. Coxib and traditional NSAID Trialists' (CNT) Collaboration. The Lancet, Volume 382, Issue 9894, Pages 769 - 779, 31 August 2013

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