European Medicines Agency starts review of ibuprofen medicines

Review to evaluate cardiovascular risk with high doses taken over long periods

The European Medicines Agency's (EMA's) Pharmacovigilance Risk Assessment Committee (PRAC) has started a review to evaluate the cardiovascular risks with systemic ibuprofen medicines (such as those taken by mouth but not topical medicines like creams and gels).

The cardiovascular risks being evaluated concern high-dose ibuprofen (2,400 mg per day) taken regularly for long periods. Ibuprofen is usually taken at lower doses and for short periods of time.

There is therefore no suggestion of a similar cardiovascular risk with ibuprofen as used by the overwhelming majority of patients. Ibuprofen is one of the most widely used medicines for pain and inflammation and has a well-known safety profile, particularly at usual doses.

More information is provided in the following hyperlink:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/06/news_detail_002125.jsp&mid=WC0b01ac058004d5c1