SAFETY OF TOPICAL IBUPROFEN GEL: ANALYSIS OF DATA FROM SPONTANEOUS REPORTING SYSTEM IN POLAND AND LITERATURE REVIEW

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Ibuprofen gel is a popular topical, over the counter, non-steroidal anti-inflammatory medication, applied directly to the skin, containing 5% ibuprofen and 3% levo-menthol, offering pain relief in various musculoskeletal problems and frequently used in field of rehabilitation including: musculoskeletal pain management, rheumatologic rehabilitation and sports medicine. Post-marketing surveillance using tools such as data mining of spontaneous (passive) reports and investigation of case reports to identify adverse drug reactions are very important in drug safety monitoring.

Objectives: To analyze the safety of ibuprofen gel (Ibum Hasco).

Materials and methods: We analyzed data obtained from monitoring of spontaneous reports of adverse effects of Ibum® topical gel collected by the manufacturer (Hasco-Lek S.A. Wroclaw, Poland) and National Monitoring Center in Warsaw in the period 2008 - July 2011. We performed a systematic literature search in the following databases: Toxnet, http://toxnet.nlm.nih.gov; Cumulative Index for Nursing and Allied Health Literature (CINAHL), http://www.ebscohost.com/cinahl; Proquest, http://www.proquest.co.uk; and Pubmed, www.ncbi.nlm.nih.gov/pubmed, using the key words: “ibuprofen topical” OR “ibuprofen gel” OR “ibuprofen local” AND “toxicity” OR “adverse effect” OR “side effect” OR “interaction” OR “risk” OR “safety” OR “carcinogenesis” in August 2011. The search was limited to a period from January 2006 to August 2011.

Results: A total 337,836 units of Ibum Gel® produced by Hasco-Lek S.A. Wroclaw, Poland was marketed during analyzed period. No spontaneous report regarding that medications was registered in Poland in that period. The literature search resulted in only one publication reporting adverse effects: a randomized controlled study of ibuprofen and arnica applied locally in patients with hand osteoarthritis, where well known adverse effects such as: skin irritation/itching in 3/99 patients, increased finger pain in 2/99 reddening of the skin in 1/99 and scaly skin in 1/99 patient in the group treated with 5% ibuprofen gel were reported.

Conclusions: Ibum topical gel containing ibuprofen and menthol is a safe medication rarely causing adverse effects. No new cases of adverse effects were reported in the last 5 years. All adverse effects of ibuprofen gel are already known or the existing spontaneous monitoring system of adverse effects has too low sensitivity and needs improvement.