SAFETY OF TOPICAL NAPROXEN 1.2% AND 10% GEL: ANALYSIS OF DATA FROM SPONTANEOUS REPORTING SYSTEM IN POLAND AND LITERATURE REVIEW

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Naproxen gel is a popular topical, over the counter, non-steroidal anti-inflammatory medication, applied directly to the skin, 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 therapy with naproxen gel (Naproxen Hasco®).

Materials and methods: We analyzed data obtained from monitoring of spontaneous reports of adverse effects of 1.2% and 10% naproxen topical gel collected by the manufacturer (Hasco-Lek S.A. Wrocław, Poland) and National Monitoring Center in Warsaw in a period from 2000 to July 2011. We performed a literature search in the following databases: Toxnet, <http://toxnet.nlm.nih.gov>; Cumulative Index to Nursing and Allied Health Literature (CINAHL); www.ebscohost.com/cinahl; Proquest, <http://www.proquest.co.uk> and Pubmed, www.ncbi.nlm.nih.gov/pubmed, using the key words: “naproxen topical” OR “naproxen gel” OR “naproxen 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 case reports in a period from January 2000 to August 2011.

Results: A total 2,155,965 units of Naproxen Hasco 1.2% gel and 9,504,928 units of Naproxen Hasco 10% gel produced by Hasco-Lek S.A. Wrocław were marketed during analyzed period. No spontaneous report regarding both medications was registered in Poland in that period. The literature search resulted in no case report of unknown adverse effects.

Conclusions: Naproxen Hasco 1.2% gel and Naproxen Hasco 10% gel are safe medications rarely causing adverse effects. No hitherto unknown side effects were reported in last 5 years so either all adverse effects of naproxen gel are already known or the existing spontaneous monitoring system of adverse effects has too low sensitivity and needs improvement.