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

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Heparin gel is a popular topical, over the counter medication, applied directly to the skin and recommended in various traumatic and venous problems such as: soft tissue injuries (swelling, contusions, post-traumatic hematoma), sports injuries (muscles strains, sprains), chronic venous insufficiency (superficial thrombophlebitis, varicose veins inflammation and post-injection phlebitis). The medication is frequently used in field of rehabilitation (sports medicine, chronic venous insufficiency). 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 heparin gel (Heparin Hasco 250 I.U./1.0g © and Heparin Hasco Forte 1000 IU/1.0g ®).

Materials and methods: We analyzed data obtained from monitoring of spontaneous reports of adverse effects of Heparin Hasco 250 I.U./1.0g® and Heparin Hasco Forte 1000 IU/1.0g® topical gel collected by the manufacturer (Hasco-Lek S.A. Wroclaw, Poland) and National Monitoring Center in Warsaw in a period from 2002 to July 2011. We performed a 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: “heparin topical” OR “heparin gel” OR “heparin 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 2006 to August 2011.

Results: A total 1,436,496 units of Heparin Hasco gel (250 I.U. heparin per 1.0 g) and 435,799 units of Heparin Hasco Forte gel (1000 I.U. heparin per 1.0 g) produced by Hasco-Lek S.A. Wroclaw 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: Heparin Hasco gel and Heparin Hasco Forte 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 heparin gel are already known or the existing spontaneous monitoring system of adverse effects has too low sensitivity and needs improvement.