SAFETY OF TOPICAL GEL CONTAINING ARNICA (MOUNTAIN TOBACCO), MARIGOLD (CALENDULA) AND HIPPOCASTANI (HORSE CHESTNUT) EXTRACTS: ANALYSIS OF DATA FROM SPONTANEOUS REPORTING SYSTEM IN POLAND AND LITERATURE REVIEW

Katarzyna Karłowicz-Bodalska¹, Stanisław Han¹, and Ernest Kuchar²
¹Department of Industrial Pharmacy and ²Department of Pediatric Infectious Diseases, Wroclaw Medical University, Wroclaw, Poland

Escalar is a popular in Poland, over the counter herbal medication in the form of a gel (containing 2 g per 100 g of spissum extract of arnica and marigold and 5 g per 100 g of dry extract of horse chestnut), applied directly to the skin, and recommended in various musculoskeletal and traumatic problems such as swelling, post-traumatic or post-surgery hematoma, chronic venous insufficiency, sports injuries and inflammation of skin and subcutaneous tissue. The medication is frequently used in the field of rehabilitation (musculoskeletal pain management, 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 arnica, marigold and hippocastani containing gel (Escalar Hasco-Lek S.A.).

Materials and methods: We analyzed data obtained from monitoring of spontaneous reports of adverse effects of gel containing arnica, calendula and horse chestnut extracts (Escalar Gel®) collected by the manufacturer (Hasco-Lek S.A. Wroclaw, Poland) and National Monitoring Center in Warsaw in a period from 1998 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), http://www.ebscohost.com/cinahl/; Proquest, http://www.proquest.co.uk; and Pubmed, www.ncbi.nlm.nih.gov/pubmed, using the key words: “arnica” OR “mountain tobacco” OR “marigold” OR “calendula” OR “Horse chestnut” OR “hippocastani” OR “aescin” 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 251,710 units of Escalar produced by Hasco-Lek S.A. Wroclaw was marketed during analyzed period. No spontaneous report regarding both 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 3/105 patients, increased finger pain in 2/105, reddening of the skin in 1/105 and allergic eczema in 1/105 in the group treated with arnica (50 g tincture/100 g, DER 1:20), as gel were reported.

Conclusions: Escalar gel containing arnica, marigold and horse chestnut extracts is a safe medication very rarely causing adverse effects. No hitherto unknown side effects were reported in the last 5 years, so probably all adverse effects of arnica, calendula and horse chestnut gel are already known or the existing spontaneous monitoring system of adverse effects may have too low sensitivity and needs improvement.