

ABSTRACT

Analysis of spontaneous adverse events reports of hypolipidemics

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Introduction: Hypolipidemic drugs are widely used in today's medicine and their consumption is still rising. Besides all benefits, their usage includes also some risks that needs to be reconsidered regularly. Analysis of spontaneous adverse effects (AEs) reports contributes to a safer therapy by detecting especially serious and unexpected adverse drug reactions.

Objective: The aim of this thesis was to analyse spontaneous adverse events reports of hypolipidemic drugs, which were sent to the State Institute for Drug Control (SÚKL) database in the period from June 2004 to October 2017.

Methods: The data obtained from SÚKL during the above mentioned period was analysed using descriptive statistics. The frequency of occurrence of certain AEs, which were categorized according to MedDRA and distinguished by hypolipidemics, was analysed, as well as their severity and expectability. Part of the analysis was for example also by whom was the report submitted and which way they used to submit it.

Results: Overall 290 reports were obtained, containing 680 AEs (on average 2.4 AEs per report). The most frequent AEs were musculoskeletal (27%), skin disorders (13%) and general disorders (9%). Statins were suspected drugs in most of the cases (84.8%). The most frequent suspected statin was atorvastatin (60% of all statins). Serious AEs were represented in 88% of reports, of which 3 cases were fatal. Congenital malformations were not reported. 16.5% of all AEs were unexpected. However, AEs disappeared without any consequences in half of the cases (51%) and were subsiding in 8.3% cases.

Conclusion: Analysis of spontaneously reported AEs of hypolipidemics provided information especially about the most frequent AEs, about their severity and expectability. Even though the majority of AEs was serious, in more than half of the cases AEs

disappeared or were subsiding. According to expectations, the most common AEs were musculoskeletal.