SAFETY OF ORAL LORATADINE – ANALYSIS OF DATA FROM A SPONTANEOUS REPORTING SYSTEM IN POLAND

Katarzyna Karlowicz-Bodalska, Ernest Kuchar, Stanislaw Han, Elzbieta Kutycka

P.P.F. Hasco-Lek S.A.

Loratadine is a popular second-generation, selective H_1 histamine antagonist used to treat allergies and marketed for its non-sedating properties. 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. **Aim:** Analysis of safety of oral loratadine (Loratan soft capsules 10 mg, Loratan syrup 5 mg/5 mL). **Material and Methods:** We analyzed data obtained from monitoring of spontaneous reports of adverse effects of Loratan soft capsules, and Loratan oral syrup 5 mg/5 mL collected by the manufacturer (Hasco-Lek S.A. Wroclaw, Poland) and National Monitoring Center in Warsaw in the period from October 2008 to June 2012. The Polish system is based mainly on written reports voluntarily submitted by professional health care workers. **Results:** A total of 2 749 288 units of Loratan soft capsules 10 mg and 789 278 units of Loratan syrup 5 mg/5 mL produced by Hasco-Lek S.A. Wroclaw, Poland were marketed during analyzed period. There was 1 spontaneous report regarding that medications registered in the analyzed period.

1. In an 82 year old woman chronically treated with several medications (Effox long, Amlozek, Doxepin, Coaxil, Clonazepam, Hydroxyzine syrup) for depression, heart coronary disease and hypertension a sudden episode of high blood pressure (to 195/105 mmHg) and tachycardia (132/minute), she was observed after she had taken a single tablet of Loratan in the evening. The symptoms did not return after cessation of Loratan.

Conclusions: Oral loratadine is a safe medication rarely causing adverse effects. Only a single case of adverse effects was reported in an almost 5 year observation period, after millions of medication units were distributed in Poland. It is possible that the existing spontaneous monitoring system of adverse effects in Poland is not sensitive enough to detect all adverse effects and needs improvement.