

SAFETY OF ORAL CLEMASTINE - ANALYSIS OF DATA FROM SPONTANEOUS REPORTING SYSTEM IN POLAND

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Clemastine is a popular first generation antihistamine and anticholinergic medication with strong antipruritic effect. Although traditional, clemastine exhibits fewer other adverse effects than most of the others older antihistamines (e.g. Brompheniramine, Chlorpheniramine, Cyproheptadine, Diphenhydramine or Triprolidine).

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 clemastine (Clemastinum Hasco tablets 1.0 mg, Clemastinum Hasco syrup 0,1 mg/mL). **Material and methods:** We analyzed data obtained from the monitoring of spontaneous reports of adverse effects of Clemastinum Hasco tablets 1.0 mg, Clemastinum Hasco syrup 0,1 mg/mL collected by the manufacturer (Hasco-Lek S.A. Wroclaw, Poland) and National Monitoring Center in Warsaw in the period from January 2007 to June 2012. The Polish system is based on written reports voluntarily submitted by professional health care workers mainly. **Results:** A total of 2 089 717 units of Clemastinum Hasco tablets 1.0 mg and 1 965 340 units of Clemastinum Hasco syrup 0,1 mg/mL produced by Hasco-Lek S.A. Wroclaw, Poland were marketed during analyzed period. There was only one spontaneous report of well known symptoms regarding Clemastinum Hasco syrup registered in analyzed period which concerned an interaction between other co-administered medicines. **Conclusions:** Oral clemastine is a safe medication rarely causing adverse effects. Only one case of adverse effects was reported in above 5 year observation period after millions of medication units were distributed in Poland. Adverse effects of clemastine are very rare or the existing spontaneous monitoring system of adverse effects in Poland is not sensitive enough and needs improvement.