SAFETY OF ORAL IBUPROFEN: ANALYSIS OF DATA FROM SPONTANEOUS REPORTING SYSTEM IN POLAND

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Ibuprofen is a very popular over-the-counter, non-steroidal anti-inflammatory medication frequently used for the relief of fever, headaches, menstrual and other minor pains as well as a major active ingredient in numerous cold preparations. Post-marketing surveillance using tools such as the 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 ibuprofen (Ibum soft capsules 0.2, Ibum Forte soft capsules 0.4, and Ibum oral suspension 100 mg/5 mL). **Material and Methods:** We analyzed data obtained from monitoring of spontaneous reports of adverse effects of Ibum soft capsules, Ibum Forte soft capsules, and Ibum oral suspension 100 mg/5 mL collected by the manufacturer (Hasco-Lek S.A. Wroclaw, Poland) and National Monitoring Center in Warsaw in the period from October 2002 to June 2012. The Polish system is based on written reports voluntary submitted by professional health care workers mainly. **Results:** A total of 19 644 797 units of Ibum soft capsules 0.2 g, 5,678,164 units of Ibum Forte soft capsules 0.4 g and 4,333,325 units of Ibum oral suspension 100 mg/5 mL (all together 29 656 286 units) produced by Hasco-Lek S.A. Wroclaw, Poland were marketed during the analyzed period. There were 5 spontaneous reports regarding that medications registered in Poland in the analyzed period.

1. An adult male reported heavy burning sensation in his mouth as well as edema and irritation of throat after chewing the capsule of IBUM FORTE, which is not recommended by the manufacturer. The symptoms subsided within about 20 minutes after gargling with water.
2. A 38 years old male complained of burning sensation of his tongue after he tasted IBUM oral suspension to check its taste.
3. An adult female complained of burning sensation of her tongue after she tasted IBUM oral suspension to check its taste.

The two above mentioned reports were received shortly after the manufacturer changed the color of IBUM oral suspension from red to white, which could have triggered anxiety in consumers.

4. A 6 years old girl, weighed 24 kg, developed generalized itching rash, prominently on her buttocks, knees and elbow crooks after she had been administered IBUM oral suspension in daily dose of 30 mL (i.e. 600 mg; 25 mg/kg) for 4 consecutive days. The girl was found to be allergic to the drug.
5. A 4 years old boy, weighed 11 kg, developed generalized urticaria (hives) shortly after a single dose of 5 mL of IBUM suspension given for the fever. The boy was found to be oversensitive to NSAID.

Conclusions: Oral ibuprofen forms are a safe medication rarely causing adverse effects. Only a few cases of adverse effects were reported in the 11 years observation period after almost 30 millions of medication units were distributed. It is possible that the existing spontaneous monitoring system of adverse effects in Poland are not sensitive enough to detect all adverse effects and needs improvement.