

## **ANAPHYLACTIC REACTIONS TO OTC ANALGESICS, PARTICULARLY PROPYPHENAZONE-COMBINATIONS**

*A.M.H. Bijl, E.P. van Puijenbroek*

Netherlands Pharmacovigilance Centre Lareb, 'S-HERTOGENBOSCH, The Netherlands

**Introduction:** The Netherlands Pharmacovigilance Centre Lareb received a substantial number of reports on anaphylactic reactions related to the use of 'over the counter' (OTC) drugs, especially analgesics. Although OTC analgesics are usually considered safe by the general public, severe anaphylactic reactions may occur.

**Aim of the Study:** To investigate if the risk of anaphylactic reactions being reported during the use of various OTC analgesics differs from the risk for these adverse drug reactions during the use of paracetamol.

**Methods:** Spontaneous reports by health professionals submitted to Lareb between January 1985 and July 1st 2004 were included. In a case/non-case design 'reporting odds ratios' (RORs) were calculated using logistic regression analysis. Cases were defined as reports in which 'anaphylactic reaction' or 'anaphylactoid reaction' or 'anaphylaxis' was reported. All other reports were considered as noncases. The index group consisted of reports that mentioned paracetamol/propyphenazone/caffeine, naproxen, diclofenac, ibuprofen, acetylsalicylic acid or carbasalate calcium as the suspect medication, the reference group consisted of reports on paracetamol.

**Results:** A total number of 2191 reports was included in the analysis. In 120 reports (5.5%) an anaphylactic reaction (including anaphylactoid reaction and anaphylaxis) was reported. Among 110 reports on paracetamol six reports were coded as an anaphylactic reaction. Of the above mentioned analgesics only one differed statistically significant compared to paracetamol. Only on the combination paracetamol/propyphenazone/caffeine relatively more anaphylactic reactions have been reported. The ROR, adjusted for the source of the reports, was 20.3 (95% CI 5.6, 73.3).

**Discussion:** On all OTC analgesics available in The Netherlands, anaphylactic reactions have been reported. The results of our study suggest that the combination of paracetamol/propyphenazone/caffeine is strongly associated with an increased risk on anaphylactic reactions compared with the use of paracetamol. In the database of the WHO Collaborating Centre for International Drug Monitoring, anaphylactic reactions are also strongly associated with propyphenazone-combinations and not with paracetamol alone or caffeine alone. Consumers should be aware that all OTC analgesics are associated with a risk of provoking severe allergic reactions.

For more information about this publication, please contact [info@lareb.nl](mailto:info@lareb.nl)