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Amoxicillin/clavulanic acid induced adverse drug reaction in a 69-year-old female patient

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Background: This report was received from a pharmacist via Medicines and Medical Devices Agency of Serbia on 2011-August-30.

Methods: case report.

Results: A 69-year-old female patient took Panklav (INN: amoxicillin / clavulanic acid) 625 mg, film-coated tablet, three times daily from 2011-08-05 to 2011-08-10 for urinary tract infection (Escherichia coli). On 2011-08-10 she experienced redness of the face, burning sensation in the stomach, urinary urgency, dark-coloured urin and fever. The outcome of the events was unknown. Suspected drug was Panklav (INN: amoxicillin / clavulanic acid) 625 mg, film-coated tablet. Therapy dates from: 2011-08-05 to 2011-08-10 (5 days). Concomitant drugs were Prilazid (INN: cilazapril), Bromazepam (INN: bromazepam), Amlogal (INN: amlodipine), Oikamid (INN: piracetam) and Zoloft (INN: sertraline). The events were assessed as medical important by the company.

Conclusions: This case was classified as non-serious. The causal relationship between amoxicillin / clavulanic acid and the suspected adverese drug reaction was assessed as possibly related based on the temporal association and the known safety profile. This case does not change the overall benefit-risk balance of the medicinal product.

Biography

Vesna V. Radovic was born on 1966-December-31 in Herceg-Novi, Yugoslavia. She enrolled the Faculty of Pharmacy in Sarajevo, completed her Masters degree at the Faculty of Biology in Belgrade, specialized pharmaceutical medicine at the Faculty of Medicine in Belgrade and completed her Ph.D at the Faculty of Medical Science in Kragujevac. She is author of five papers published in journals with international review and five papers published in the national journals. She has published more than 45 statements. Member of the Pharmaceutical Society of Serbia. She works in STADA.

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