



Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/
Adverse Event Information

Medical Safety
Information

No.145, December 2018

Administration of the Usual Dosage of Drugs for Patients with Impaired Renal Function

Eight cases have been reported in which a patient with reduced renal function was affected when administered the usual dosage of drugs whose package insert stated that a reduced dosage or cautious administration was required in such patients. (information collection period: from January 1, 2014 to October 31, 2018). This information was compiled on the basis of the content featured in the Analysis Themes section of the 52nd Quarterly Report.

Cases have been reported in which a patient with reduced renal function was affected when administered the usual dosage of drugs necessitating a reduced dosage or cautious administration in such patients.

Efficacy Classification	Name of Drug Administered	Number of Cases
Antiviral chemotherapeutic	Valtrex Tablets 500	4
	Valaciclovir Tablets 500 mg	
Antiarrhythmic	Cibenol Tablets 100 mg	1
	Pilsicainide Hydrochloride Capsules*	1
Broad spectrum oral antibiotic	Cravit Tablets 500 mg	1
Therapeutic agent for osteoporosis (Activated vitamin D ₃ preparation)	Edirol Capsules 0.75 µg	1

*Specification unknown.

Administration of the Usual Dosage of Drugs for Patients with Impaired Renal Function

Case 1

The physician decided to prescribe Valtrex tablets to a patient with shingles who had had an outpatient consultation at night. Although the physician had ascertained from the medical history that the patient was receiving dialysis, they were not aware that it was necessary to reduce the dosage, so the physician prescribed the usual usage and dosage of Valtrex tablets 500 mg 2 tablets per dose, 3 times/day. The patient was admitted two days later after experiencing slurred speech and visual hallucinations.

Case 2

The physician had not ascertained that the patient was receiving dialysis, so continued to prescribe Cravit tablets 500 mg 1 tablet per dose, 1 time/day. The patient subsequently experienced severe vomiting and was found to have pancytopenia. The Cravit tablets were suspected to be the cause, so administration was halted.

Preventive measures taken at the medical institutions in which the events occurred

- Physicians will ascertain the patient's renal function before prescribing drugs and prescribe a dosage appropriate to that patient's renal function.
- Pharmacists will check the patient's renal function when dispensing drugs that are metabolized and excreted by the kidneys.

* As part of the Project to Collect Medical Near-Miss/Adverse Event Information (a Ministry of Health, Labour and Welfare grant project), this medical safety information was prepared based on the cases collected in the Project as well as on opinions of the "Comprehensive Evaluation Panel" to prevent the occurrence and recurrence of medical adverse events. See the Project website for details.

<http://www.med-safe.jp/>

* Accuracy of information was ensured at the time of preparation but cannot be guaranteed in the future.

* This information is intended neither to limit the discretion of healthcare providers nor to impose certain obligations or responsibilities on them.

