Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.45, August 2010

Bone marrow suppression due to antirheumatic (Methotrexate) overdose (1st Follow-up Report)

Information regarding bone marrow suppression due to antirheumatic (Methotrexate) overdose was released as Medical Safety Information No.2 (January 2007). After that time, two similar cases was reported, so the information is provided here again. (information collection period: from October 1, 2006 to June 30, 2010)

Methotrexate prescribed as an antirheumatic drug, requires a drug holidays.

《Administration example》

The package sheet of methotrexate has improved (image)

Methotrexate capsule 2mg "○○○○"

Please take this drug only on the determined days in a week.

_____month_____day
( )
Morning ・ Evening

This drug requires drug holidays, please be warned of that when taking drug.

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Case

Administration of Rheumatrex capsules was started for the first time for the patient with for rheumatoid arthritis. The physician failed to enter the designated day of the week on the computer prescription, and erroneously input 21-day continuous administration. The correct prescription was to be every Tuesday for three weeks (three days of administration, totaly). There was a simple verbal explanation to the patient that the drug was to be taken once a week, and the prescription was issued. At the pharmacy as well, Rheumatrex capsules for 21-day were provided without explanation regarding administration method. As a result, the patient administered Rheumatrex capsules everyday as prescribed. When the primaly physician in charge noticed the prescription error, the patient manifested symptoms such as bone marrow suppression and was admitted to the hospital for treatment.

The methotrexate products used as antirheumatic drug

・Methotrexate tablets 2mg ・Metolate tablets 2mg ・Trexamette 2mg
・Methotrexate capsules 2mg ・Rheumatrex capsules 2mg

The ministry of Health, Labour and Welfare has issued notification regarding erroneous administration (overdose) of antirheumatic drug (Methotrexate).

○ Issued by the Safety Division of the Pharmaceutical and Food Safety Bureau, No.0829001, August 29, 2008
○ Issued by the General Affairs Dvision of the Health Policy Bureau, No.1020001, October 20, 2008
Issued by the General Affairs Dvision of the Pharmaceutical and Food Safety Bureau, No.1020001, October 20, 2008
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Complementary comment by the Comprehensive Evaluation Panel

Clearly mark the drug holidays, such as using a column for the date of taking drug time on the package sheet of the medicine.

* 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 "Comprehensive Evaluation Panel" to prevent occurrence and recurrence of medical adverse events. See quarterly reports and annual reports posted on the Japan Council for Quality Health Care website for details of the Project. http://www.med-safe.jp/
* Accuracy of information was ensured at the time of preparation but can not be guaranteed in the future.
* This information is neither for limiting the discretion of healthcare providers nor for imposing certain obligations or responsibilities on them.

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