



Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/
Adverse Event Information

Medical Safety Information

No.57, August 2011

Accidental ingestion of PTP sheets

Fourteen cases of taking medicine without removing the PTP sheets, have been reported (information collection period: from January 1, 2007 to June 30, 2011; the information is partly included in “Individual Theme Review” (p.100) in the 23rd Quarterly Report).

Cases of taking medicine without removing the PTP sheets have been reported.

Image of Case 1

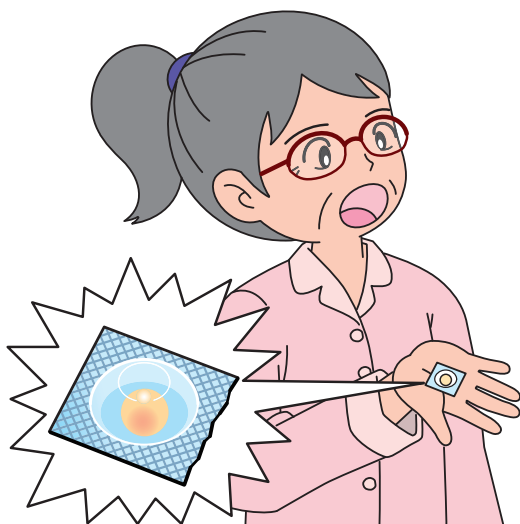


Image of Case 2



- ◆ PTP (Press Through Package) sheets are packages where medicine is wrapped in plastic or aluminum.
- ◆ Six cases out of fourteen reported cases selected “mental disorder,” “disturbance of consciousness,” or “dementia/amnesia,” as the patient condition just before the case occurred.

Accidental ingestion of PTP sheets

Case 1

The hospitalized patient swallowed an Alfarol capsule as is, without taking it out of the PTP sheet. The medicine was removed from the upper esophagus by endoscope.

Case 2

The nurse brought oral medicine to the patient and put the contents out of the one-dose package, and Harnal and Aricept still in PTP sheets, into the medicine cup. The patient swallowed the medicine and the medicine in PTP sheets together at the same time. Afterwards, gastroendoscopy was performed.

The ministry of Health, Labour and Welfare has issued notification regarding measures to prevent accidental ingestion of PTP sheets.

- Issued by the General Affairs Division of the Health Policy Bureau, No.0915-2, the General Affairs Division of the Pharmaceutical and Food Safety Bureau, No.0915-5, the Safety Division of the Pharmaceutical and Food Safety Bureau, No.0915-1, September 15, 2010
- Issued by the Safety Division of the Pharmaceutical and Food Safety Bureau, No.0915-3, September 15, 2010

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

- Unless necessary, do not separate the PTP sheets into individual tablets.
- Provide medicine in one-dose package form as much as possible, depending on the understanding ability of the patient.
- Warn the patient of accidental ingestion of PTP sheets.

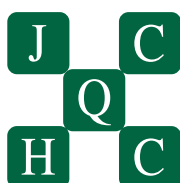
Complementary comment by the Comprehensive Evaluation Panel

- When distributing medicine, do not give medicine in different forms, such as medicine wrapped in PTP sheets and one-dose packaged medicine, at the same time.
- Explain to the patient the risk of accidental ingestion of the each piece of PTP sheet with a tablet which was cut out from the whole sheet.

* 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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