



Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/
Adverse Event Information

Medical Safety Information

No.77, April 2013

Vasculitis due to administration of gabexate mesilate (1st Follow-up Report)

Information about the extravascular leakage of gabexate mesilate was provided in Medical Safety Information No.33 (August 2009), which stated that eight cases had been reported over a period of three and a half years. As 11 similar cases have been reported over the subsequent three and a half years, information about this issue is provided here again. (information collection period: from July 1, 2009 to February 28, 2013).

Ten of the reported cases involved administration via a peripheral blood vessel in concentrations greater than 0.2%, despite the fact that the package insert states "If administering via a peripheral blood vessel, it is preferable to administer an intravenous infusion with a concentration of no more than 0.2%."

Drug Concentration	Number of Cases
$\leq 0.2\%$	1*
$0.2\% <$	10

* The case in which the concentration was $\leq 0.2\%$ involved extravasation.

Concentration of gabexate mesilate administered via a peripheral blood vessel

0.3%	1 case
0.4%	4 cases
0.6%	2 cases
3.1%	2 cases
4.2%	1 case

- ◆ The package insert for gabexate mesilate states "the use of this drug at high concentrations can damage the inner wall of blood vessels and cause phlebitis, induration, ulceration and necrosis at the injection site and along the blood vessel into which it is inserted, so when administering this drug via a peripheral blood vessel, it is preferable to carry out an intravenous infusion of 100mg of this drug in at least 50mL of fluid (no more than 2%)." Please check the package insert for details regarding the use of this drug.
- ◆ This is the 1st follow-up report regarding extravascular leakage of gabexate mesilate, following Medical Safety Information No.33.

Vasculitis due to administration of gabexate mesilate (1st Follow-up Report)

Case

Administration of parenteral nutrition and Reminaron 1,500mg / normal saline 48mL (concentration 3.1%) via a double lumen central venous line was started. Subsequently, an order was received to add antibiotics and a blood transfusion, but although a route was secured via a peripheral blood vessel on the dorsum of the right hand, it was 22G, which was too narrow, so it was decided to administer the blood transfusion via the central vein. As blood transfusions and Reminaron should be administered separately, in principle, administration of Reminaron was switched to the peripheral blood vessel route, but the concentration was left unchanged. Redness and swelling subsequently appeared on the dorsum of the right hand and the patient was seen in the dermatology department, but the ulceration and necrosis had spread, so debridement was carried out.

Gabexate mesilate products

Agalit 100

Gabexate Mesilate 100mg (Sawai)

FOY 100

Panabate 100 for inj.

Probitor for inj. 100mg

Mechuroseiteo 100mg

Reminaron 100mg

Gabexate Mesilate 500mg (Sawai)

FOY 500

Panabate 500 for inj.

Probitor for inj. 500mg

Mechuroseiteo for injection 500mg

Reminaron 500mg

*From PMDA, Information on Package Inserts for Prescription Drugs (as of February 28, 2013)

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

- Staff will be made thoroughly aware of the fact that the concentration of the infusion must be no more than 0.2% (an infusion of at least 50mL per 100mg of the drug) when administering gabexate mesilate via a peripheral blood vessel.

Complementary comment by the Comprehensive Evaluation Panel

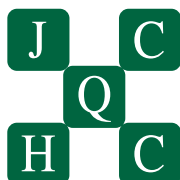
- It is preferable for the concentration of gabexate mesilate to be no more than 0.2%, if it is to be administered via a peripheral blood vessel.
- Pay attention to the concentration when switching the administration route from a central vein, etc. to a peripheral blood vessel.

* 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 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 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.



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