



This is a joint project with the Pharmaceuticals and Medical Devices Agency (PMDA). Please also refer to PMDA Medical Safety Information No. 68 February 2024 "Precautions for Blood Purification in Patients Receiving ACE Inhibitors."

Use of Blood Purifiers Contraindicated in Patients Receiving ACE Inhibitors

Cases have been reported in which patients were affected by the use of blood purifiers contraindicated in patients receiving angiotensin converting enzyme inhibitors (ACE inhibitors).

Three such cases were reported between January 1, 2021 and December 31, 2023. This information was compiled on the basis of the content featured in the Details of Events section of the 70th Quarterly Report.

Brand Name	Number of Cases	Main Background Factors of Reported Events
Rheocarna	3	<ul style="list-style-type: none"> -The physician did not know that the use of Rheocarna in patients receiving ACE inhibitors is contraindicated because it may cause shock, and therefore did not order a drug holiday. -The therapy was being administered at the medical institution for the first time, but the nephrology department did not share information with the department of cardiovascular medicine about the start date of the therapy, and did not discuss a drug holiday for the ACE inhibitor.

Blood purifiers contraindicated in patients receiving ACE inhibitors (as of December 31, 2023)

Japanese Medical Device Nomenclature	Brand Name	Marketing Authorization Holder
Parallel-plate dialyzer	H12 Hemodialyzer	Baxter Limited
Selective plasma component adsorber	Immusorba	Asahi Kasei Medical Co., Ltd.
	Immusorba TR	
Adsorption plasma perfusion column	Selesorb	Kaneka Corporation
	Liposorber (LA-S)	
	Liposorber LA-15	
Adsorption hemoperfusion column	Rheocarna	

◆ The [Contraindications] section in each of the aforementioned products' package inserts states that the use of the product in patients receiving ACE inhibitors may cause shock.

Use of Blood Purifiers Contraindicated in Patients Receiving ACE Inhibitors

Case 1

Hemoadsorption therapy using Rheocarna was to be administered at the medical institution for the first time, to a patient with arteriosclerosis obliterans who was receiving an ACE inhibitor. The physician did not know that the use of Rheocarna in patients receiving ACE inhibitors is contraindicated because it may cause shock, and therefore did not order a drug holiday. The patient took an ACE inhibitor on the morning of the therapy. Six minutes after starting the therapy, the patient's blood pressure fell to 87/38 mmHg, so the physician provided replacement fluid with normal saline, but the patient's blood pressure subsequently fell to 50/37 mmHg and their level of consciousness declined. The physician immediately halted the hemoadsorption therapy, added replacement fluid, and administered oxygen.

Case 2

Hemoadsorption therapy using Rheocarna was to be administered to a patient with critical limb-threatening ischemia who was receiving an ACE inhibitor. The therapy was being administered at the medical institution for the first time, but the department of cardiovascular medicine and the nephrology department did not discuss a drug holiday for the ACE inhibitor. Ten minutes after starting the therapy, the patient complained of feeling unwell and their blood pressure fell to 75/38 mmHg.

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

- Create a mechanism for checking whether the patient is receiving an ACE inhibitor before starting therapy with a blood purifier that is contraindicated for combined use with ACE inhibitors (particularly before the first time).
- Share information with departments involved in blood purification therapy about blood purifiers contraindicated in patients receiving ACE inhibitors.

The measures above are examples. Please consider initiatives suitable for your own facility.

PMDA Medical Safety Information No. 68 February 2024 "Precautions for Blood Purification in Patients Receiving ACE Inhibitors" can be viewed at the URL below.

<https://www.pmda.go.jp/files/000266722.pdf>

* 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.

<https://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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