Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Hydroxyethylated starch 70000
Hydroxyethylated starch 70000/sodium chloride/potassium chloride/calcium chloride hydrate/sodium lactate

January 12, 2023

Therapeutic category

Blood substitutes

Non-proprietary name

Hydroxyethylated starch 70000

Hydroxyethylated starch 70000/sodium chloride/potassium chloride/calcium chloride hydrate/sodium lactate

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Contraindications (N/A)	Contraindications Patients with severe sepsis [The condition of patients may be exacerbated.]
Precautions for Indications This drug should not be used for relative decreased blood volume during the management of critically ill patients including patients with severe sepsis.	Precautions for Indications This drug should not be used for relative decreased blood volume during the management of critically ill patients.
(N/A)	Careful Administration Patients with sepsis (excluding patients with severe sepsis) [If the disease becomes severe, the condition of patients may be exacerbated.]
Other Precautions In overseas clinical studies, it has been reported that the use of HES preparations note) in patients with severe sepsis was associated with a higher mortality risk at 90 days after administration and a higher percentage of patients requiring renal replacement therapy, as compared with the use of acetated Ringer's solution. It has been also reported that the use of HES	Other Precautions In overseas clinical studies, it has been reported that the use of HES preparations note) in patients with severe sepsis (having infection, meeting the systemic inflammatory response syndrome (SIRS) criteria, and having at least one organ dysfunction [= SOFA score of 3 or more]) was associated with a higher mortality risk at 90 days after administration and a higher percentage of patients

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preparations in patients admitted to the ICU including patients with sepsis was associated with a higher percentage of patients requiring renal replacement therapy, as compared with the use of saline, although the mortality risk up to 90 days after administration did not increase. note) HES preparations with different molecular weights or degrees of substitution, etc. from those of this drug	requiring renal replacement therapy, as compared with the use of acetated Ringer's solution. It has been also reported that the use of HES preparations in patients admitted to the ICU including patients with sepsis was associated with a higher percentage of patients requiring renal replacement therapy, as compared with the use of saline, although the mortality risk up to 90 days after administration did not increase. note) HES preparations with different molecular weights or degrees of substitution, etc. from those of this drug

N/A: Not Applicable. No corresponding language is included in the current Precautions.

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