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Translated by
Pharmaceuticals and Medical Devices Agency



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions

Amicaliq Infusion Solution

Paresafe Infusion Solution

Pareplus Infusion Solution

June 25, 2020

Therapeutic category

Protein and amino acid preparations

Non-proprietary name

Not applicable

Safety measure

Precautions should be revised in the package insert.

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
<p>Contraindications Patients with serious renal disorder or azotaemia</p> <p>(N/A)</p> <p>Patients with hyperkalaemia, <u>oliguria</u>, or Addison's disease</p> <p>Careful Administration (N/A)</p> <p>Important Precautions (N/A)</p>	<p>Contraindications Patients with serious renal disorder or <u>patients with azotaemia (for both, patients on dialysis or hemofiltration are excluded)</u></p> <p><u>Patients with oliguria (patients on dialysis or hemofiltration are excluded)</u></p> <p>Patients with hyperkalaemia or Addison's disease</p> <p>Careful Administration <u>Patients on dialysis or hemofiltration with serious renal disorder, azotaemia, or oliguria</u></p> <p>Important Precautions <u>The volume of water, electrolytes, or urea, etc. removed and accumulated in patients on dialysis or hemofiltration with serious renal disorder, azotaemia, or oliguria varies depending on the dialysis method and patients' conditions. Initiation and continuation of administration should be determined after the patient's conditions are carefully checked based on assessment of blood biochemistry, acid-base equilibrium, and body-fluid balance, etc.</u></p>

N/A: Not Applicable, because the section is not included in the current package insert.

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