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Revision of Precautions

Pntwin No.1, Pntwin No.2, Pntwin No.3 Infusion Solution

Fulcaliq 1, Fulcaliq 2, Fulcaliq 3 Infusion Solution

Onepal No.1, Onepal No.2 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

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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 Patients with hyperkalaemia, oliguria, Addison's disease, or azotaemia	Contraindications Patients with hyperkalaemia or Addison's disease
Patients with serious renal disorder	Patients with serious renal disorder or patients with azotaemia (for both, patients on dialysis or hemofiltration are excluded)
(N/A)	Patients with oliguria (patients on dialysis or hemofiltration are excluded)
Careful Administration (N/A)	Careful Administration Patients on dialysis or hemofiltration with serious renal disorder, azotaemia, or oliguria
Important Precautions (N/A)	Important Precautions 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.

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

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