

September 24, 2024

**Otsuka Pharmaceutical Factory obtains marketing approval of
“KIDPAREN[®] Injection,” the amino acid, glucose, electrolyte, fat, and
multivitamin injection for high calorie parenteral nutrition of patients
with chronic kidney disease**

Otsuka Pharmaceutical Factory, Inc. (Head Office: Naruto, Tokushima, Japan; President and Representative Director: Shuichi Takagi; hereinafter, “Otsuka Pharmaceutical Factory”) has obtained the marketing approval of “KIDPAREN[®] Injection,” the amino acid, glucose, electrolyte and multivitamin injection for high calorie parenteral nutrition of patients with chronic kidney disease.

This product is a kit formulation of total parenteral nutrition that combines amino acids, glucose, electrolytes (excluding potassium and phosphorus) and vitamins (in accordance with the FDA 2000 formulation^{*1}) in a 1,050 mL 3-chamber bag that provides 1,500 kcal and is directed at the patients with chronic kidney disease who need to restrict fluid.

Total parenteral nutrition (TPN) is also called high calorie nutrition. It is a method of administering concentrated nutrition solution through a major central vein close to the heart and is used for patients in poor nutritional conditions or who are unable to eat and drink for a long period of time (not less than a week).

Oral or enteral feeding of the patients with chronic kidney disease may be impossible or insufficient due to various complications, etc.,^{*2} and they may have to depend on TPN, a combination of TPN base solution for kidney disease, amino acid solution for kidney disease, TPN multivitamin, electrolytes, etc. However, this method has posed a problem that the feeding volume tends to be large to provide necessary nutrients.

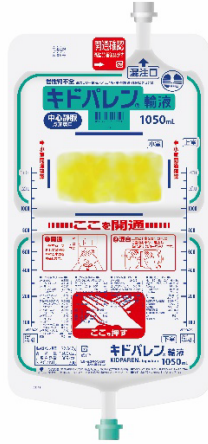
This Product, with the volume of solution reduced as much as possible, satisfies the energy requirements set in the Dietary Recommendations for Chronic Kidney Disease^{*3}, and supplies amino acids to build as much protein as possible, glucose, electrolytes (except potassium and phosphorus), and vitamins (in accordance with the FDA 2000 formulation). It enables preparation of mixing various ingredients aseptically by breaking the center seal before use. We hope this Product will allow more options of injections for TPN management of the patients with chronic kidney disease and reduce the burden on the healthcare setting.

Otsuka Pharmaceutical Factory will continue to promote R&D to contribute to proper nutrition management and aim to be the best partner for patients and healthcare professionals in the field of clinical nutrition.

Based on the corporate philosophy of “Otsuka-people creating new products for better health worldwide,” the Otsuka Group is dedicated to contributing to the health of people around the world.

- *1. Vitamin formulation for parenteral nutrition issued by the Food and Drug Administration (FDA) in 2000.
- *2. Gastrointestinal bleeding, aspiration pneumonia, bile capsule inflammation, consciousness disorder by cerebrovascular disorders, mental eating disorders, anorexia by uremia, diarrhea (severe), ileus, disuse syndrome, preoperative and postoperative care, etc.
- *3. Edited by the Japanese Society of Nephrology: Dietary Recommendations for Chronic Kidney Disease 2014, The Japanese Journal of Nephrology, 2014; 56 (5): 553-599

Product Information

Brand name	KIDPAREN® Injection
Regulatory classification	Prescription drug
Storage	Store at room temperature, protected from light
Date of approval	September 24, 2024
Indications	Provision of water, electrolytes, calories, amino acids, and vitamins for patients with chronic kidney disease who are unable or difficult to take nutrients orally or enterally and have to depend on total parenteral nutrition (limited to those with or likely to have hyperkalemia or hyperphosphatemia)
Packaging	 <p>1,050 mL×10 bags</p>
Expiration date	18 months

Company Profile

Otsuka Pharmaceutical Factory, Inc.

Established : October 7, 1969 (founded September 1, 1921)
 Capital : 80 million yen
 Representative : Shuichi Takagi, President, and Representative Director
 Head Office : 115 Kuguhara, Tateiwa, Muya-cho, Naruto, Tokushima 772-8601, Japan
 Employees : 2,318 (as of December 31, 2023)
 Business : Manufacture, sale, import and export of pharmaceuticals, medical devices, and functional foods with a focus on clinical nutritional products.
 URL : <https://www.otsukakj.jp/en/>