

September 25, 2020

**Otsuka Pharmaceutical Factory obtains marketing approval of  
ENEFLUID® Injection, the amino acid, glucose, electrolyte, fat, and  
water-soluble vitamin injection**

Otsuka Pharmaceutical Factory, Inc. (Head Office: Naruto, Tokushima, Japan; President and Representative Director: Shinichi Ogasawara; “OPF”) has obtained the marketing approval of “ENEFLUID® Injection,” the amino acid, glucose, electrolyte, fat, and water-soluble vitamin injection on September 25, 2020.

This product is the first peripheral parenteral nutrition solution in Japan that combines fat and water-soluble vitamins in addition to glucose, electrolytes, and amino acids in a dual-chamber bag. By compounding fat, more calories can be administered than the approved glucose, electrolyte, and amino acid infusions, and by compounding nine water-soluble vitamins (in accordance with the FDA 2000 formulation<sup>1</sup>) required for peripheral parenteral nutrition, nutrition can be managed with a single agent for approximately 1 to 2 weeks.

Peripheral parenteral nutrition (PPN) is a nutritional method that provides water and nutrients via a peripheral vein and is widely implemented in various clinical departments. Glucose, electrolyte, and amino acid infusions, commonly used as representative peripheral parenteral nutrition solutions, have low calories to be used as the main source of nutrition for patients in nutritional management for approximately 2 weeks, which is generally an indication for PPN; therefore, an intravenous fat emulsion is used concomitantly as needed in medical practice.

However, the intravenous fat emulsion is a drug that requires caution in its use, as mixing it with other drugs is contraindicated in terms of concerns of compatibility and prevention of bacterial contamination. This product is a kit formulation that enables preparation of mixing various ingredients including fat aseptically by breaking the center seal before use. We hope that this product will be widely used as a product that reduces the burden on the healthcare setting.


OPF 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.

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<sup>1</sup> Vitamin formulation for parenteral nutrition issued by the Food and Drug Administration (FDA) in 2000.

## Product Information

|                           |   |
|---------------------------|---|
| Brand name                | ENEFLUID® Injection   |
| Regulatory classification | Prescription drug   |
| Storage                   | Store at room temperature.  |
| Date of approval          | September 25, 2020  |
| Indications               | Provision of amino acids, electrolytes, calories, fatty acids, water-soluble vitamins, and water in the following instances:<br>- Mild hypoproteinemia or mild malnutrition due to inadequate oral intake<br>- Before and after surgery |
| Packaging                 |  <p style="text-align: center;">550 mL × 20 bags                      1100 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 | : Shinichi Ogasawara, President and Representative Director  |
| Head Office    | : 115 Kuguhara, Tateiwa, Muya-cho, Naruto, Tokushima 772-8601, Japan   |
| Employees      | : 2,247 (as of December 31, 2019).   |
| Business       | : Manufacture, sale, import and export of clinical nutrition products and other pharmaceutical products, medical devices, functional foods, etc. |
| Description    |  |
| URL            | : <a href="https://www.otsukakj.jp/en/">https://www.otsukakj.jp/en/</a>  |