

July 5, 2016

**Otsuka Pharmaceutical Factory obtained
the manufacturing and marketing approval of
“ELNEOPA-NF No. 1 Injection and ELNEOPA-NF No. 2 Injection”**

Otsuka Pharmaceutical Factory, Inc. (Head Office: Naruto, Tokushima, Japan; President: Shinichi Ogasawara) obtained the manufacturing and marketing approval of “ELNEOPA-NF No. 1 Injection and ELNEOPA-NF No. 2 Injection,” the glucose, electrolyte, amino acid, multivitamin, and trace element injection for central vein infusion, on July 4, 2016.

“ELNEOPA-NF No. 1 Injection and ELNEOPA-NF No. 2 Injection” are quad-bag kit formulations consisting of dual chambers (upper and lower chamber solutions), the mini chamber V (a vitamin solution) and mini chamber T (a trace element solution) placed inside the upper chamber. These products reduce the risks such as forgetting to add trace nutrients (vitamins and trace elements) and microbial contamination during the mixing procedure.

In “ELNEOPA No. 1 Injection and ELNEOPA No. 2 Injection” launched in 2009, the vitamins were formulated based on the 1975 AMA formulation^{*1} and the trace elements were based on the existing formulation of trace element preparations for TPN.^{*2}

Recently, however, the daily requirements of various nutrients in parenteral nutrition have been reviewed and the guidelines have been revised accordingly. Concerning vitamin requirements, in the U.S., the FDA 2000 formulation, a new formulation issued by the Food and Drug Administration (FDA) in 2000, has become widespread, instead of the 1975 AMA formulation. As of 2016, all commercially available vitamin preparations in the U.S. have been formulated in accordance with the FDA 2000 formulation. In addition, the guidelines of A.S.P.E.N.^{*3} in the U.S. and ESPEN^{*4} in Europe have been revised regarding trace elements.

Given this background, we developed “ELNEOPA-NF No. 1 Injection and ELNEOPA-NF No. 2 Injection,” the new formula of already marketed ELNEOPA Injections. In ELNEOPA-NF Injections, the amounts of vitamins B¹, B⁶, C, and folic acid were increased and the amounts of vitamin K and iron were decreased, referring to the formulation widely adopted overseas. We expect these products will be highly useful in clinical practice.

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 “Guidelines for Multivitamin Preparations for Parenteral Use” issued by American Medical Association (AMA) in 1975

*2 Total parenteral nutrition

*3 American Society for Parenteral and Enteral Nutrition

*4 European Society for Clinical Nutrition and Metabolism

Product Information

Brand name	ELNEOPA-NF No. 1 Injection	ELNEOPA-NF No. 2 Injection	
Regulatory classification	Prescription drug		
Storage	Store at room temperature, protected from light		
Approval No.	22800AMX00422000	22800AMX00423000	
Date of approval	July 4, 2016		
Indications	Provision of water, electrolytes, calories, amino acids, vitamins, zinc, iron, copper, manganese, and iodine in patients who require central venous nutrition because oral or enteral nutrition is inadequate or not possible		
Packaging	 <p>1000 mL × 10 bags</p>	 <p>1000 mL × 10 bags</p>	
	 <p>1500 mL × 5 bags</p>	 <p>1500 mL × 5 bags</p>	
	 <p>2000 mL × 5 bags</p>	 <p>2000 mL × 5 bags</p>	

Company Profile

Otsuka Pharmaceutical Factory, Inc.

Established	:	October 7, 1969
Capital	:	80 million yen
President	:	Shinichi Ogasawara, President and Representative Director
Head Office	:	115 Kuguhara, Tateiwa, Muya-cho, Naruto, Tokushima 772-8601, Japan
Employees	:	2,335 (as of December 31, 2015)
Business Description	:	Manufacture and sale of drugs (mainly clinical nutrition products), medical devices, and functional foods
URL	:	http://www.otsukakj.jp/