

June 2, 2014

**Otsuka Pharmaceutical Factory launches
“RACOL-NF Semi Solid for Enteral Use”
on June 2, 2014**

Tokyo, Japan, June 2, 2014– Otsuka Pharmaceutical Factory, Inc. (Head Office; Naruto-shi, Tokushima, Japan: President; Ichiro Otsuka: “OPF”) launches a newly approved enteral nutrition formula “RACOL-NF Semi Solid for Enteral Use” on June 2, 2014. “RACOL-NF Semi Solid for Enteral Use” is the first semi-solid enteral nutrition formula as a prescription drug.

The active ingredients and their contents per calorie are same as those for “RACOL-NF Liquid for Enteral Use,” which is widely used in clinical practice. “RACOL-NF Semi Solid for Enteral Use” is a polymeric enteric nutrition formula which appropriately contains major nutrients, vitamins, minerals, and trace elements based on the typical Japanese nutrition intake pattern.

At current clinical practice, enteral nutrition formulas are sometimes administered via gastric fistula after they are prepared to be semi-solid using certain additives. Such administration method using a semi-solid enteral nutrition formula of which physical property is similar to that of usual diet is expected to induce the innate physiological gastric motility.

Also, such method is thought to be effective to decrease the adverse reactions caused by liquid enteral nutrition formulas and the time required to administer liquid enteral nutrition formulas.

However, several disadvantages of the method, such as the risk of contamination during preparation and difficulties of maintaining a stable quality have been pointed out, and the development of ready-to-use semi-solid enteral nutrition formulas as prescription drug has been required in clinical practice.

“RACOL-NF Semi Solid for Enteral Use” could decrease the possibility of contamination risk during preparation and secure a certain level of quality such as chemical and physical properties.

Also, this product can be administered in a shorter time than the case of liquid enteral nutrition formulas, and its efficacies and safety are equivalent to those for “RACOL-NF Liquid for Enteral Use.”

Decrease of the time required for the administration is resulted in reducing the patient-restraint time, which might increase the rehabilitation time and reduce the workload of nursing staff and caregivers.

OPF strives to be the best partner in clinical nutrition worldwide by continuously providing information and products which are useful for proper nutrition management.

Product Information

Brand name	RACOL-NF Semi Solid for Enteral Use
Category	Enteral nutrition formula (prescription drug)
Packaging	18 bags/case 
Indications	Usually, this product can be used to maintain nutritional status in postoperative patients; in particular it is intended for nutrition support by tube feeding in patients with difficulty in ingesting food over the long term. ≪Precautions≫ When adequate nutrient intake by oral feeding has become possible, promptly change to oral nutrition.
Dosage and administration	The usual adult dosage is in the reference range of 1,200-2,000 g (1,200-2,000 kcal)/day in several feedings into the stomach through a gastrostomy tube. This product should be administered 100 g/2-3 minutes (300 g/6-9 minutes). The maximum amount per feeding should be 600 g. Patients should carefully be observed after the initial feeding. The feeding amount should be escalated with care to clinical symptoms and should reach the reference range within several days. Amounts and durations of feeding should appropriately be adjusted depending on the age, weight, and symptom.

	<p>«Precautions»</p> <p>This product is enteral formula; it must not be administered intravenously.</p>
Storage	<p>1) Avoid freezing storage and storing at temperature higher than room temperature.</p> <p>2) After opening, keep protected from microbial contamination and direct sunlight and use up as soon as possible.</p>
Expiration date	13 months after the manufacturing
Date of approval for manufacturing and marketing	March 24, 2014
Date of NHI drug price listing	May 30, 2014
Price	8.40 JPY/10 g (252 JPY/300g-bag)
Manufactured and Distributed by	EN Otsuka Pharmaceutical Co., Ltd.
Co-marketed by	Otsuka Pharmaceutical Co., Ltd., Otsuka Pharmaceutical Factory, Inc.

Company Profile

Otsuka Pharmaceutical Factory, Inc.

Established	:	September 1, 1921
Capital	:	80 million yen
President	:	Ichiro Otsuka, President and Representative Director
Head Office	:	115 Kuguhara, Tateiwa, Muya-cho, Naruto, 772-8601 Tokushima, Japan
Employees	:	2,343 (as of March 31, 2014)
Business Description	:	Manufacture and sale of pharmaceutical and nutrition products
URL	:	http://www.otsukakj.jp/