

THE FDgard[®]

DIFFERENCE

FDgard utilizes SST[®] (Site-Specific Targeting) technology to deliver solid-state, triple-coated, targeted-release microspheres of caraway oil and I-Menthol, quickly and reliably where they are needed most in FD – the upper belly.

Microspheres of Caraway Oil and I-Menthol

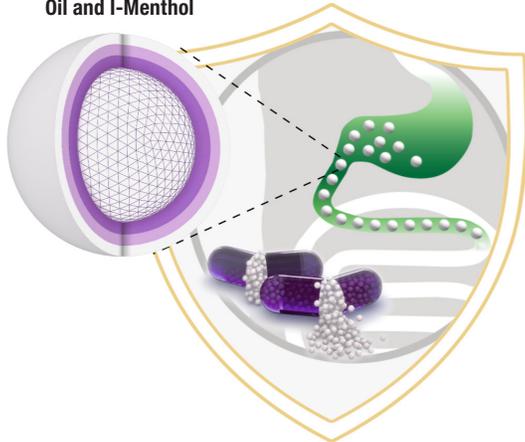


Illustration of solid-state, targeted-release, triple-coated microspheres acting in the upper belly (SST[®] delivery)

For more information visit FDgard.com.
*Use under medical supervision.

For Distribution by Healthcare Professionals Only.



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Available in 12 and 36 count cartons.
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Meals Triggering Indigestion?†

You may be the 1 in 6 living with Functional Dyspepsia (FD).¹⁻³



ABDOMINAL PAIN
DISCOMFORT
DIFFICULTY
FINISHING A MEAL
BLOATING NAUSEA[†]

FDgard[®] - The PreMeal Companion[®]

FDgard is a medical food specially formulated for the dietary management of FD.*

What Is Functional Dyspepsia (FD)?

FD (recurring indigestion[†]) is typically meal-triggered and is a relatively common and often frustrating condition. About one in six Americans has Functional Dyspepsia¹⁻³. FD is often described as non-ulcer dyspepsia. FD is an underdiagnosed⁴ and/or undermanaged condition. FD is a disorder of sensation and movement in the organs of the upper digestive tract where the normal downward pumping and squeezing is altered. The **intake** and **uptake** (i.e., ingestion, digestion and absorption) of food nutrients can be affected. FD symptoms can remit and then relapse, and often can last over 10 years⁴.

FD symptoms occur in the upper belly, above the navel. In FD, the stomach does not expand normally in response to a meal, which means the food eaten backs up in the stomach and in the upper part of the small intestine³.



What Causes FD?

In the absence of a known organic cause, it is thought that FD is associated with the disruption in the lining of the gut (gut mucosal barrier) and reversible, localized, often temporary, low-grade immune activation, which can result in the impaired **intake** and **uptake** (i.e., ingestion, digestion and absorption) of food nutrients⁵⁻⁷. Common triggers are food⁸, stress⁹, and the environment¹⁰. If FD is suspected, consult with a physician about confirming FD and then developing a program to manage it.



What Are The Distinctive Nutritional Requirements For People Who Have FD?

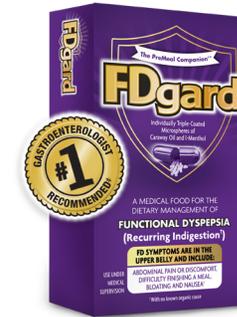
People with FD often do not eat regularly or normally, which may affect their normal **intake** of nutrients. Also, the **uptake** (i.e., digestion and absorption) is affected due to disturbances in the GI tract. Dietary modification alone, as a management strategy, has had mixed success, especially with long-term adherence.

Now physicians increasingly use medical foods, such as FDgard, to help normalize the **intake** and **uptake** (i.e., ingestion, digestion and absorption) of food nutrients, and to help manage FD symptoms.

What Is FDgard?

FDgard is a medical food specially formulated for the dietary management of Functional Dyspepsia (FD). The combination of caraway oil and peppermint oil (primary component: l-Menthol) has been shown in several clinical studies to be effective in helping manage FD¹¹.

In addition to caraway oil and l-Menthol, FDgard also provides fiber and amino acids (from gelatin protein).



Usual Adult Dosage

As directed by a physician. Take two capsules, two times a day. Take 30 to 60 minutes before a meal, with water. If the pre-meal dose is missed, FDgard can be taken when needed. Do not exceed six capsules per day. Swallow capsules whole, or open capsules and mix contents with applesauce. Do not chew.

* Use under medical supervision.

[†] With no known organic cause.

[‡] Among gastroenterologists who recommended herbal products for FD. IQVIA ProVoice survey (June 2019).

¹ Talley, Nicholas J. 2017. "Functional Dyspepsia : Advances in Diagnosis and Therapy." *Gut and Liver* 11 (3): 349–57.

² Voiosu TA, Giurcan R, Voiosu AM, Voiosu MR. Functional dyspepsia today. *Maedica - a J Clin Med.* 2013;8(1):68-74. doi:10.1097/00001574-200411000-00007.

³ Kindt S, Tack J. Impaired gastric accommodation and its role in dyspepsia. *Gut.* 2006;55(12):1685-1691. doi:10.1136/gut.2005.085365.

⁴ Talley NJ, Ford A. Functional Dyspepsia. *N Engl J Med.* 2015;373(19):1853-1863. doi:10.1056/NEJMra1501505.

⁵ Pleyer C, Bittner H, Locke GR, et al. Overdiagnosis of gastro-esophageal reflux disease and underdiagnosis of functional dyspepsia in a USA community. *Neurogastroenterol Motil.* 2014;26(8):1163-1171. doi:10.1111/nmo.12377.

⁶ Stanghellini, Vincenzo, Francis K L Chan, William L. Hasler, Juan R. Malagelada, Hidekazu Suzuki, Jan Tack, and Nicholas J. Talley. 2016. "Gastrointestinal Disorders." *Gastroenterology* 150 (6). Elsevier, Inc: 1380–92. doi:10.1053/j.gastro.2016.02.011.

⁷ Walker, Marjorie M., and Nicholas J. Talley. 2017. "The Role of Duodenal Inflammation in Functional Dyspepsia." *Journal of Clinical Gastroenterology* 51 (1): 12–18. doi:10.1097/MCG.0000000000000740.

⁸ Feinle-Bisset, Christine, and Fernando Azpiroz. 2013. "Dietary and Lifestyle Factors in Functional Dyspepsia." *Nature Reviews Gastroenterology & Hepatology* 10 (3). Nature Publishing Group: 150–57. doi:10.1038/nrgastro.2012.246.

⁹ Aro, Pertti, Nicholas J. Talley, Jukka Ronkainen, Tom Storskrubb, Michael Vieth, Sven Erik Johansson, Elisabeth Bolling-Sternevald, and Lars Agr us. 2009. "Anxiety Is Associated With Uninvestigated and Functional Dyspepsia (Rome III Criteria) in a Swedish Population-Based Study." *Gastroenterology* 137 (1). AGA Institute American Gastroenterological Association: 94–100. doi:10.1053/j.gastro.2009.03.039.

¹⁰ Wildner-Christensen, Mette, Jane Moller Hansen, and Ove B Schaffalitzky De Muckadell. 2006. "Risk Factors for Dyspepsia in a General Population: Non-Steroidal Anti-Inflammatory Drugs, Cigarette Smoking and Unemployment Are More Important than Helicobacter Pylori Infection." *Scandinavian Journal of Gastroenterology* 41 (2): 149–54. doi:10.1080/00365520510024070.

¹¹ Thompson Coon, J, and E Ernst. 2002. "Systematic Review: Herbal Medicinal Products for Non-Ulcer Dyspepsia." *Alimentary Pharmacology & Therapeutics* 16 (10): 1689–99. doi:10.1046/j.0269-2813.2002.01339.x.