

October 24, 2025

EA Pharma Co., Ltd.

EA Pharma Filed Application for Additional Dosage and Administration of “MOVICOL® LD” and
“MOVICOL® HD” for Chronic Constipation in 1-Year Old Pediatric Patients in Japan

EA Pharma Co., Ltd. (Head Office, Chuo-ku, Tokyo, Japan; President, Hidenori Yabune; “EA Pharma”) announces that EA Pharma filed yesterday an application for marketing and manufacturing approval of additional dosage and administration of “MOVICOL® LD” and “MOVICOL® HD” (collectively “MOVICOL®”) for chronic constipation in 1-year old pediatric patients in Japan.

MOVICOL® is the first polyethylene glycol indicated for treatment of chronic constipation¹⁾ in Japan, approved for use in children of 2 years and above and adults²⁾. In overseas countries, this product has been marketed under the brand name of *MOVICOL** mainly in Europe and widely used in pediatric and adult patients with chronic constipation. In 15 European countries, *MOVICOL* is approved for use in children of 1 year old. In order to meet the treatment needs of chronic constipation in Japan, EA Pharma has developed MOVICOL® to add the dosage and administration for pediatric use in 1-year-old children.

The application of this time is based on the results of clinical studies that EA Pharma conducted for investigation of efficacy and safety of dosage and administration in pediatric patients of 1 year of age with chronic constipation in Japan.

Chronic constipation is a very common disease in children. The patients and their families often suffer from a decline of QOL (Quality of Life). In pediatric chronic constipation, it is reported that diagnosis and treatment at an early stage can result in an improved prognosis ^{a)}.

EA Pharma is striving to add the dosage and administration for pediatric patients of 1 year of age as it seeks to further contribute to addressing the needs of, and increasing the benefits provided to, patients with chronic constipation, their families and healthcare providers.

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- 1) Excluding structural disease-induced constipation
- 2) Please see the electronic package insert for proper use guidance.

【References】

- a) Guideline for Diagnosis of Chronic Functional Constipation in Pediatrics 2025 edited by Japanese Society for Pediatric Gastroenterology, Hepatology and Nutrition and Japanese Society for Pediatric Neurogastroenterology; p.v, 9-10, SHINDAN TO CHIRYO SHA, Inc. 2025

1. About “MOVICOL® LD” and “MOVICOL® HD”

MOVICOL® is an orally-available chronic constipation treatment agent, in-licensed from Norgine (headquartered in the Netherlands) to EA Pharma. MOVICOL® increases the water retention in the intestinal tract by osmolality of its main ingredient polyethylene glycol (macrogol 4000), which increases fecal moisture, softens feces, increases fecal volume and physiologically activates the peristaltic movement of the colon to promote bowel movement. EA Pharma made a joint development and marketing agreement with Mochida Pharmaceutical Co., Ltd. (Head office, Shinjuku-ku, Tokyo, Japan; President, Naoyuki Mochida) for MOVICOL®, and the two companies started the distribution in Japan of MOVICOL® LD (formerly “MOVICOL®”) as of November 29, 2018 and MOVICOL® HD as of May 20, 2022 under the same brand name, respectively.

2. About EA Pharma Co., Ltd.

EA Pharma Co., Ltd., a subsidiary of Eisai Co., Ltd. for gastrointestinal disease area, was established in April 2016 by integration of the gastrointestinal business unit with more than 60 year's history of the Eisai Group and the gastrointestinal business unit of the Ajinomoto Group having amino acid as its business core. EA Pharma is a gastrointestinal specialty pharma with a full value chain covering R&D, logistics and sales & marketing.

For more information on EA Pharma Co., Ltd., please see <https://www.eapharma.co.jp/en/>

* “MOVICOL” is a registered trademark of the Norgine group.

(In this document, *MOVICOL* means the product marketed in non-Japan countries.)