

# News Release

September 16, 2026

EA Pharma Co., Ltd.

## **Additional Dosage and Administration of “MOVICOL® LD” and “MOVICOL® HD” Approved 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”) today announced that EA Pharma has obtained the 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 constipation<sup>1)</sup> in Japan, approved for use in children of 2 years and above and adults. 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 and the UK, *MOVICOL* is approved for use in children of 1 year old.

With this approval, the age indication of MOVICOL® has been expanded from the current “2 years and above” to “one year and above”<sup>2)</sup>.

This approval is based on the result of a clinical study 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. The clinical study demonstrated the efficacy and safety profile of MOVICOL® in pediatric patients aged 1 year.

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 <sup>a)</sup>. With this approval, MOVICOL® becomes available for use in children of 1 year old and above, which provides another treatment option for younger pediatric patients suffering from chronic constipation.

EA Pharma seeks to further contribute to addressing the needs of, and increasing the benefits provided to, patients with chronic constipation, their families and healthcare providers.

1) Excluding structural disease-induced constipation

2) Please see the electronic package insert for proper use guidance.

\* “MOVICOL” is a registered trademark of the Norgine group. (In this document, *MOVICOL* means the product marketed in non-Japan countries.)

《Source》

- 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

| Media Inquiries                                                                                                                        |
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| EA Pharma Co., Ltd.<br>Corporate Communication Dept.<br>Mail: <a href="mailto:contact_ea@eapharma.co.jp">contact_ea@eapharma.co.jp</a> |

《More Information》

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 started the distribution of MOVICOL® LD (formerly “MOVICOL®”) as of November 29, 2018 and MOVICOL® HD as of May 20, 2022 in Japan.

**Details of the present approval (The underlined parts are added.)**

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| Indication                | Chronic constipation (excluding structural disease-induced constipation)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Dosage and administration | <p>Dissolve this powdered medicine in water and administer orally.</p> <p><u>For children aged 1 year, normally 1 sachet of MOVICOL® LD (“LD”) should be administered orally at once per day for the initial dose. Then, the dose can be increased or decreased depending on symptoms, administered orally once or twice per day. The maximum daily dose is 2 sachets of LD or 1 sachet of MOVICOL® HD (“HD”), (up to 2 LD sachets or 1 HD sachet at once). An interval of at least 2 days is needed between every dose escalation, and the dose should not be increased in excess of 1 LD sachet per day.</u></p> <p>For children aged 2-6 years, normally 1 sachet of LD should be administered orally at once per day for the initial dose. Then, the dose can be increased or decreased depending on symptoms, administered orally 1-3 times per day. The maximum daily dose is 4 sachets of LD or 2 sachets of HD, (up to 2 LD sachets or 1 HD sachet at once). An interval of at least 2 days is needed between every dose escalation, and the dose should not be increased in excess of 1 LD sachet per day.</p> <p>For children aged 7-11 years, normally 2 LD sachets or 1 HD sachet should be administered orally at once per day for the initial dose. Then, the dose can be increased or decreased depending on symptoms, administered orally 1-3 times per day. The maximum daily dose is 4 LD sachets or 2 HD sachets (up to 2 LD sachets or 1 HD sachet at once). An interval of at</p> |

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|  | <p>least 2 days is needed between every dose escalation, and the dose should not be increased in excess of 1 LD sachet per day.</p> <p>For adults and children aged 12 years and older, normally 2 LD sachets or 1 HD sachet should be administered orally at once per day for the initial dose. Then, the dose can be increased or decreased depending on symptoms, administered orally 1-3 times per day. The maximum daily dose is 6 LD sachets or 3 HD sachets (up to 4 LD sachets or 2 HD sachets at once). An interval of at least 2 days is needed between every dose escalation, and the dose should not be increased in excess of 2 LD sachets or 1 HD sachet per day.</p> |
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## 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/>