May 20, 2022

EA Pharma Co., Ltd.
Eisai Co., Ltd.
Mochida Pharmaceutical Co., Ltd.

# “MOVICOL® HD” Launched
## - A New Dosage Form Added to Polyethylene Glycol Chronic Constipation Treatment for the First Time in Japan -

EA Pharma Co., Ltd. (President, Hidenori Yabune; Headquarters, Chuo-ku, Tokyo, Japan, “EA Pharma”), EA Pharma’s parent company Eisai Co., Ltd. (CEO, Haruo Naito; Headquarters, Bunkyo-ku, Tokyo, Japan, "Eisai") and Mochida Pharmaceutical Co., Ltd. (President, Naoyuki Mochida; Headquarters, Shinjuku-ku, Tokyo, Japan, “Mochida”) announced today that “MOVICOL® HD”, a chronic constipation treatment, was launched by EA Pharma and Mochida.

MOVICOL® HD is a high dose formulation of existing “MOVICOL® LD”, the first polyethylene glycol indicated for treatment of chronic constipation[1)] in Japan. MOVICOL® HD contains the same active ingredients in double the quantity of MOVICOL® LD per sachet. For the patients who have previously used 2 sachets of MOVICOL® LD per dose, MOVICOL® HD can save the time and effort of opening multiple sachets, increasing convenience, reducing the economic burden and reducing packing waste.

MOVICOL® LD and MOVICOL® HD (collectively “MOVICOL®”) are indicated for children of 2 years and above and adults patients[2)]. MOVICOL® is a powdered medicine to be dissolved in water before administration, which enables suitable increase or decrease of the dose to obtain the preferred stool consistency. 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.


Outside Japan, MOVICOL® has been marketed in mainly in Europe by Norgine B.V. (Headquarters, the Netherlands, "Norgine") under the brand name *MOVICOL** and is used by many patients with chronic constipation. In Japan, the Evaluation Committee on Unapproved or Off-Labeled Drugs with High Medical Needs[3)] of Ministry of Health, Labour and Welfare recognized the "high unmet medical needs" of polyethylene glycol preparations for chronic constipation, and Ajinomoto Pharmaceuticals Co., Ltd. (now EA Pharma) developed MOVICOL® with Mochida for oral chronic constipation treatment in pediatric and adult patients in Japan under the license granted by Norgine to Ajinomoto Pharmaceuticals Co., Ltd. (now EA Pharma).

EA Pharma and Mochida start today distribution of MOVICOL® HD under the same brand name in Japan. EA Pharma and Eisai jointly provide information for the proper use of MOVICOL® HD under a co-promotion agreement.

The prevalence of constipation is high in young women and both elderly men and women, and the symptoms can become severe particularly in pediatric patients[a)b)]. The symptoms of constipation include reduced bowel movement, feeling of incomplete evacuation, and hard stools. When the symptoms become chronic, many patients suffer from a decline of QOL (Quality of Life)[c)]. With the new dosage form MOVICOL® HD in addition to "GOOFICE® 5 mg Tablet" (bile acid transporter inhibitor for chronic constipation[1)] treatment) and MOVICOL® LD (polyethylene glycol), EA Pharma, Eisai and Mochida are striving to increase treatment options for patients with chronic constipation and diverse disease histories as they seek to further contribute to addressing the needs of, and increasing the benefits provided to, patients, their families and healthcare providers.

1) Excluding structural disease-induced constipation
2) Please see the package insert for proper use guidance.
3) The Evaluation Committee on Unapproved or Off-Labeled Drugs with High Medical Needs
   This committee was organized in the Ministry of Health, Labour and Welfare to evaluate the medical needs of the drugs and indications that are not approved in Japan ("unapproved or off-labeled drugs") and the appropriateness of filing the public knowledge-based application and requirement of additional studies for filing the marketing and manufacturing application to promote development of unapproved or off-labeled drugs by pharmaceutical companies.

【References】


a) Rates of people who have subjective symptoms of constipation by age and gender, Comprehensive Survey of Living Conditions 2016, Ministry of Health, Labour and Welfare
b) Guideline for Diagnosis of Chronic Functional Constipation in Pediatrics edited by Japanese Society for Pediatric Gastroenterology, Hepatology and Nutrition and Japanese Society for Pediatric Neurogastroenterology; p.23-24, SHINDAN TO CHIRYO SHA, Inc. 2013
c) Tomita T, Miwa H. *JGH* 2020 Oct 13. doi: 10.1111/jgh.15295.



| Media Inquiries | | |
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More Information

**1. "MOVICOL® LD, MOVICOL®HD" Product Outline**

<table>
<tr><td>Brand name</td><td>MOVICOL® LD, MOVICOL® HD</td></tr>
<tr><td>Ingredients</td><td>macrogol 4000, sodium chloride, sodium bicarbonate, potassium chloride</td></tr>
<tr><td>Formulation<br>Contents</td><td>Powdered preparation for oral fluid
<table>
<tr><td rowspan="2">Active ingredients</td><td colspan="2">MOVICOL®</td></tr>
<tr><td>LD<br>1 sachet（6.8523g）</td><td>HD<br>1 sachet（13.7046g）</td></tr>
<tr><td>Macrogol 4000</td><td>6.5625 g</td><td>13.1250 g</td></tr>
<tr><td>Sodium chloride</td><td>0.1754 g</td><td>0.3508 g</td></tr>
<tr><td>Sodium bicarbonate</td><td>0.0893 g</td><td>0.1786 g</td></tr>
<tr><td>Potassium chloride</td><td>0.0251 g</td><td>0.0502 g</td></tr>
</table></td></tr>
<tr><td>Indication</td><td>Chronic constipation (excluding structural disease-induced constipation)</td></tr>
<tr><td>Dosage<br>and administration</td><td>Dissolve this powdered medicine in water and administer orally.<br><br>For children aged 2-6 years, 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 1-3 times per day. The maximum daily dose is 4 sachets of LD or 2 sachets 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.<br><br>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 least 2 days is needed between every dose escalation, and the dose should not be increased in excess of 1 LD sachet per day.<br><br>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.</td></tr>
</table>

(continued on following page)

<table>
<tr><td>Dosage<br>and administration</td><td>
<table>
<tr><th rowspan="2">Age</th><th colspan="2" rowspan="2">Dose</th><th colspan="2">MOVICOL®</th></tr>
<tr><th>LD</th><th>HD</th></tr>
<tr><td rowspan="4">2-6 years</td><td colspan="2">Initial dose</td><td>1 sachet</td><td>—</td></tr>
<tr><td colspan="2">Maximum dose escalation* per day</td><td>1 sachet</td><td>—</td></tr>
<tr><td rowspan="2">Maximum dose per day</td><td>Per dose</td><td>2 sachets</td><td>1 sachet</td></tr>
<tr><td>Per day</td><td>4 sachets</td><td>2 sachets</td></tr>
<tr><td rowspan="4">7-11 years</td><td colspan="2">Initial dose</td><td>2 sachets</td><td>1 sachet</td></tr>
<tr><td colspan="2">Maximum dose escalation* per day</td><td>1 sachet</td><td>—</td></tr>
<tr><td rowspan="2">Maximum dose per day</td><td>Per dose</td><td>2 sachets</td><td>1 sachet</td></tr>
<tr><td>Per day</td><td>4 sachets</td><td>2 sachets</td></tr>
<tr><td rowspan="4">12 years and above, Adults</td><td colspan="2">Initial dose</td><td>2 sachets</td><td>1 sachet</td></tr>
<tr><td colspan="2">Maximum dose escalation* per day</td><td>2 sachets</td><td>1 sachet</td></tr>
<tr><td rowspan="2">Maximum dose per day</td><td>Per dose</td><td>4 sachets</td><td>2 sachets</td></tr>
<tr><td>Per day</td><td>6 sachets</td><td>3 sachets</td></tr>
</table>
*An interval of at least 2 days is needed between every dose escalation.
</td></tr>
<tr><td>Packaging</td><td>100 sachets</td></tr>
<tr><td>National Health Insurance Drug (NHI) Price</td><td>MOVICOL® LD 1 sachet ¥75.30<br>MOVICOL® HD 1 sachet ¥131.60</td></tr>
<tr><td>Date of manufacture and marketing approval</td><td>MOVICOL® LD September 21, 2018<br>MOVICOL® HD January 25, 2021</td></tr>
<tr><td>Date of inclusion in the NHI drug price list</td><td>MOVICOL® LD November 20, 2018<br>MOVICOL® HD November 25, 2021</td></tr>
<tr><td>Launch</td><td>MOVICOL® LD November 29, 2018<br>MOVICOL® HD May 20, 2022</td></tr>
<tr><td>Manufacturer and distributor</td><td>EA Pharma Co., Ltd.</td></tr>
<tr><td>Promotion alliance with EA Pharma Co., Ltd.</td><td>Eisai Co., Ltd.</td></tr>
<tr><td>Distributor</td><td>Mochida Pharmaceutical Co., Ltd.</td></tr>
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## 2. About “GOOFICE® 5 mg Tablet”

“GOOFICE® 5 mg Tablet”, which EA Pharma in-licensed from Albireo AB (Headquarters, Sweden), is an orally available chronic constipation* treatment having a novel mechanism of action. “GOOFICE® 5 mg Tablet” inhibits the bile acid transporter that regulates reabsorption of bile acids thereby increasing the flow of bile acids to the colon, which is expected to enhance colonic motility. EA Pharma and Mochida have a joint development and marketing agreement for “GOOFICE® 5 mg Tablet”, and started distribution of “GOOFICE® 5 mg Tablet” respectively under the same brand name on April 19, 2018 in Japan. EA Pharma also has a co-promotion agreement with Eisai. EA Pharma and Eisai jointly provide information for the proper use of “GOOFICE® 5 mg Tablet”.

*Excluding structural disease-induced constipation

## 3. 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/

## 4. About Eisai Co., Ltd.

Eisai Co., Ltd. is a leading global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which we call our human health care (*hhc*) philosophy. With approximately 10,000 employees working across our global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our *hhc* philosophy by delivering innovative products to address unmet medical needs, with a particular focus in our strategic areas of Oncology and Neurology.
For more information on Eisai Co., Ltd., please see https://www.eisai.com/

## 5. About Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. has been committed to research and development of innovative pharmaceutical products since its establishment thereby providing distinctive medicines to the medical field. Currently, the core pharmaceutical business focuses resources on the targeted areas of cardiovascular medicine, obstetrics and gynecology, psychiatry and gastroenterology, while also providing medicine for intractable disease as well as generics including biosimilars, to meet medical needs.
For more information on Mochida Pharmaceutical Co., Ltd., please see https://www.mochida.co.jp/english/

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