News Release



August 18, 2025

Mochida Pharmaceutical Co., Ltd.

The NHI Drug Price Listing and Launch of LIALDA Tablets 600mg, a Treatment for Ulcerative Colitis, in Japan

Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan, President: Naoyuki Mochida, hereinafter: Mochida) announced that LIALDA Tablets 600mg (generic name: mesalazine, hereinafter: the product) as the new formulation of LIALDA, a therapeutic agent for ulcerative colitis, will be launched on September 8, 2025, as the NHI (National Health Insurance) Drug Price was listed on August 14, 2025.

By MMX[®] technology¹⁾, LIALDA is one of 5-aminosalicylic acid preparations designed to continuously release the active ingredient to and throughout the colon which is the target site. This allows LIALDA to be once-daily oral administration in both active and remission phases of ulcerative colitis. Mochida in-licensed LIALDA from Shire Pharmaceuticals Group in 2009²⁾ and has been marketing it in Japan as a treatment for ulcerative colitis since 2016.

The product has been developed, being smaller and more flexible in dosing options based on weight than LIALDA Tablets 1200mg.

Mochida believes that the product will contribute to improving the quality of life of patients with ulcerative colitis.

- 1) MMX® technology is a drug delivery system (DDS) designed to achieve sustained release of active ingredient to and throughout the colon.
- 2) The License Agreement for LIALDA was transferred to Takeda Pharmaceuticals U.S.A., Inc. in 2023.

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[References]

Summary of LIALDA Tablets 600mg

Brand Name : LIALDA Tablets 600mg

Generic Name : mesalazine

Ingredients and Contents : Film-coated Tablet

600mg mesalazine per tablet

Indications : Ulcerative colitis (excluding severe cases)

Dosage and Administration : The usual oral dosage of this product in adults is 2,400 mg of

mesalazine once daily after meals. In the active stage, the oral dosage of this product in adults is 4,800 mg of mesalazine once daily after meals. The dosage may be reduced according to patients' age and

symptoms.

The usual oral dosage of this product in pediatric patients weighing over 23 kg is 40 mg/kg of mesalazine once daily after meals. The maximal dose should be 2,400 mg per day. In the active stage, the oral dosage of this product in pediatric patients weighing over 23 kg is 80 mg/kg of mesalazine once daily after meals. The maximal dose should

be 4,800 mg per day. The dosage may be reduced according to

patients' age and symptoms.

Package : 100 tablets [10 tablets(PTP)×10]

NHI Drug Price : 96.10 Yen per tablet

Approved Date : June 24, 2025

NHI Drug Price Listing Date : August 14, 2025

Scheduled Launch Date : September 8, 2025

Manufacturer / Distributor : Mochida Pharmaceutical Co., Ltd.

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shall prevail.