

Company name : KYORIN Holdings, Inc.
Representative Director, President : Minoru Hogawa
Securities Code : 4569, TSE 1st Sec.

NHI Drug Price Listing of PENTASA[®] Granules 94%, a treatment for Ulcerative Colitis and Crohn's Disease

TOKYO, Japan (December 11, 2015) — Kyorin Pharmaceutical Co., Ltd. (“Kyorin”) (Head office: Chiyoda-ku, Tokyo, President: Mitsutomo Miyashita), a wholly owned subsidiary of KYORIN Holdings, Inc., announced today that Ulcerative Colitis and Crohn's Disease treatment drug of “PENTASA[®] Granules 94%” has been listed on the National Health Insurance (NHI) drug price. In addition, the launch of the product is scheduled for release in December. The product received marketing authorization from the Ministry of Health, Labour and Welfare in August 2015.

Kyorin Pharmaceutical has been working to develop novel dosage forms and to gain approval of novel administration and dosage to satisfy the therapeutic needs of patients with inflammatory bowel diseases (ulcerative colitis and Crohn's disease). To date, the company has released Pentasa[®] Tablets 250 mg, Pentasa[®] Tablets 500 mg, Pentasa[®] Enema 1 g, and Pentasa[®] Suppositories 1 g. Pentasa[®] Granules 94% is a granular agent developed for patients who have difficulty taking pills because of the large size of the oral mesalazine tablet or the need to ingest multiple pills. With substantially decreased dosage, achieved by increasing the mesalazine content to 94% using the company's own technology, this agent will enable patients to take oral medication in one dose with a single stick (a maximum of 2000 mg of mesalazine), when a large quantity of mesalazine is required with each dose. We believe these advantages will encourage greater therapeutic compliance.

Kyorin Pharmaceutical has added Pentasa[®] Granules 94% to its existing lineup of dosage forms. Moving forward, it will continue to provide the latest information as it works to support the treatment of patients with inflammatory bowel disease.

The sales of the drug is factored in consolidated forecast for the fiscal year ending March 31 2016.

< Product photo >



< Product information >

1. Brand name	PENTASA [®] Granules 94%
2. Active ingredient	Mesalazine
3. Indications	Ulcerative colitis (excluding severe cases), and Crohn's disease
4. Dosage and administration	<p>Ulcerative colitis:</p> <p>The usual oral dosage of this product in adults is 1,500 mg of mesalazine daily in three divided doses after meals, in the remission stage, however, this product may be administered once daily, as required. The dosage may be adjusted according to patients' ages and symptoms, with the upper limit of 2,250 mg daily. In the active stage, however, this product may be administered in a daily dose of 4,000 mg in two divided portions, as required. The usual oral dosage of this product in children is 30 to 60 mg/kg of mesalazine daily in three divided doses after meals. The dosage may be adjusted according to patients' ages and symptoms, with the upper limit of 2,250 mg daily.</p> <p>Crohn's disease:</p> <p>The usual oral dosage of this product in adults is 1,500 to 3,000 mg of mesalazine daily in three divided doses after meals. The dosage may be reduced according to patients' ages and symptoms. The usual oral dosage of this product in children is 40 to 60 mg/kg of mesalazine daily in three divided doses after meals. The dosage may be adjusted according to patients' ages and symptoms.</p>
5.NHI Price :	94%1g ¥164.90
6. Packaging	<p>Boxes of 100 packets</p> <p>(250mg*×100 packets) (500mg*×100 packets)</p> <p>(1000mg*×100 packets) (2000mg*×100 packets) ※Mesalazine</p>
7.Date of Drug Price Listing :	December 11, 2015
8.Date of initial marketing in Japan	By the end of December, 2015