

To Whom It May Concern

KYORIN Co.,Ltd

Approval for an additional regimen and dose of Pentasa[®] for the treatment of ulcerative colitis in its active phase.

Tokyo—December 24,2008,KYORIN Co., Ltd. announces that its wholly owned subsidiary, KYORIN Pharmaceutical Co., Ltd.(Headquarters :Tokyo, President :Itaru Kojo) obtained approval for an additional regimen and dose (4,000 mg divided into two doses per day) of Pentasa[®] Tablets 250 and Pentasa[®] Tablets 500 (generic name: mesalazine) for the treatment of ulcerative colitis in its active phase. These products are intended for the treatment of ulcerative colitis and Crohn's disease.

Inflammatory bowel diseases (ulcerative colitis and Crohn's disease) are intractable diseases that hinder social interaction, causing frequent diarrhea and melena. The causes have not been identified and there is no radical treatment. Therefore, the therapeutic goals are suppressing symptoms in the active phase, alleviating the symptoms and keeping the symptoms in a relieved state with the use of mesalazine drugs like Pentasa and steroids.

In adult patients with less-severe ulcerative colitis, 1,500 mg is usually divided into three post-meal oral doses per day. The upper limit of the daily dose was 2,250 mg. The validity of the daily dose of 4,000 mg has been verified overseas. Based on this fact, KYORIN Pharmaceutical Co., Ltd. decided to develop the above regimen and dose with the aim of giving new remission therapy to patients who had to switch to steroids or other treatments because of their active-phase disease and the difficulty in controlling their symptoms with the conventional upper dose limit. The new regimen and dose were also intended to provide patients with greater convenience.

A domestic dose-comparison study on active-phase ulcerative colitis in adults showed a significant difference between patients receiving 4,000 mg and those receiving 2,250 mg in the degree of improvement of the UC-DAI score*, an important laboratory parameter.

By obtaining approval of the addition, KYORIN Pharmaceutical Co., Ltd. will continue to contribute to the treatment of ulcerative colitis and increase the clinical value of Pentasa[®].

*UC-DAI score

UC : ulcerative colitis

DAI score : disease activity index score

Frequency of bowel evacuation, blood in stool, endoscopic findings of mucous membranes and doctor's overall evaluation are each rated at one of four levels, 0 to 3. The sum of the numbers is the DAI score (0-12).

For further information, contact:

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Products Profile

1.Brand name	Pentasa® Tablets 250	Pentasa® Tablets 500
2.Nonproprietary name	Mesalazine	
3.Indication	Ulcerative colitis (excluding severe cases) and Crohn's disease	
4.Dosage and Administration	<p>Ulcerative Colitis</p> <p>Normally, for adult patients, a daily dose of 1,500 mg is divided into three doses and is administered orally after meals. The dose may be decreased or increased according to the age and symptoms while the upper limit is 2,250 mg per day.</p> <p><u>In an active phase, however, 4,000 mg can be divided into two doses per day if required.</u></p> <p>Normally, for infant patients, a daily dose of 30 to 60 mg/kg of mesalazine is divided into three doses and administered orally after meals. The dose may be decreased or increased according to the age and symptoms while the upper limit is 2,250 mg per day.</p> <p>Crohn's Disease</p> <p>Normally, for adult patients, a daily dose of 1,500-3,000 mg is divided into three doses and is administered orally after meals. The dose may be decreased according to the age and symptoms.</p> <p>Normally, for infant patients, a daily dose of 40 to 60 mg/kg of mesalazine is divided into three doses and administered orally after meals. The dose may be decreased or increased according to the age and symptoms.</p> <p><u>Precautions for use regarding regimen and dose</u></p> <p><u>1. The increase of the daily dose to 4,000 mg must be limited to patients with ulcerative colitis that is moderate and categorized as a relapse/remission type, not a proctitis type.</u></p> <p><u>2. Neither the efficacy nor safety of administering 4,000 mg/day for eight weeks has been established. Stay sufficiently updated on the patient's condition and avoid unnecessarily allowing the daily dose of 4,000 mg to be continued.</u></p>	
5.NHI price	¥59.40 per tablet	¥118.80 per tablet
6.Packaging	PTP 100,500 tablets	PTP 100 tablets

Reference:

1.Bland name	Pentasa® Enema 1g
2.Indications	Ulcerative colitis (excluding severe cases)
3.Dosage and Administration	Normally, for adult patients, a bottle (1 g mesalazine) as a daily dose is injected through the rectal route. The dose may be decreased according to the age and symptoms.
4.NHI price	¥872.90 per bottle (1g)
6.Packaging	100 ml ×7