Kyorin Co., Ltd. Nisshin Kyorin Pharmaceutical Co., Ltd.

Pentasa® Tablets 250 Received Approvals For Additional Pediatric Indication

Nisshin Kyorin Pharmaceutical Co., Ltd. that had approval for manufacturing and marketing of Pentasa acquired pediatric indication for Pentasa® Tablets 250 (generic name: mesalazine) on February 29.

Pentasa is a therapy for ulcerative colitis and Crohn's disease that is currently distributed by Kyorin Pharmaceutical Co., Ltd. (Tokyo; President: Ikuo Ogihara), subsidiaries of Kyorin Co., Ltd. and Nisshin Kyorin Pharmaceutical Co., Ltd. (Tokyo; President: Takashi Matsuda)

Nisshin Kyorin Pharmaceuticals Co., Ltd. conducted clinical trials in Japan for the drug developed by Ferring (Switzerland). Pentasa was designated as an orphan drug in November 1993 and was approved for manufacturing and marketing as an agent for ulcerative colitis and Crohn's disease in April 1996. Kyorin Pharmaceutical Co., Ltd. and Nisshin Kyorin Pharmaceutical Co., Ltd. marketed the drug in July 1996. Since then, the companies have contributed to the treatment of ulcerative colitis and Crohn's disease. Approval for pediatric indication will further satisfy the need for treatment of inflammatory bowel diseases.

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 basic remedy. Therefore, therapeutic goals are suppressing symptoms in the active phase, alleviating the symptoms and keeping the symptoms in the relieved state with the use of Pentasa and other mesalazine drugs and steroids. In addition, it has been hoped that added indications in pediatrics would be provided because inflammatory bowel diseases occur even in childhood, affecting children's growth and learning.

Pentasa has extensive use experience in other countries: the indication for the drug for ulcerative colitis in adults has already been approved in 43 countries, and for Crohn's disease in 39 countries, and the indication for inflammatory bowel diseases in infants has been approved in 20 countries.

The profile of Pentasa® Tablets 250 is as follows:

- (1) A preparation made from 5-aminosalicylate (5-ASA)
- (2) A release-controlled preparation coated with ethylcellulose

Kyorin Pharmaceutical Co., Ltd. and Nisshin Kyorin Pharmaceutical Co., Ltd. will continue to contribute to the treatment of inflammatory enteric diseases by continuously providing the latest information on Pentasa and inflammatory bowel diseases.

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Products Profile

1 Toddets 1 Toffic	
1. Brand name	Pentasa® Tablets 250
2. Nonproprietary name	Mesalazine
3. Indication	Ulcerative colitis (excluding severe cases) and Crohn's
	disease
4. Dosage and	Ulcerative Colitis
Administration	Normally, for adult patients, the daily dose of 1500 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 2250 mg per day.
	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 2250 mg per day.

	Crohn's Disease
	Normally, for adult patients, a daily dose of 1500-3000
	mg of mesalazine is divided into three doses and
	administered orally after meals. The dose may be
	decreased according to the age and symptoms.
	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.
5. NHI price	¥61.50 per tablet
6. Packaging	PTP 100,500 tablets

Reference:

1. Brand name	Pentasa® Enema 1g
2. Indications	Ulcerative colitis (excluding severe cases)
3 Dosage and	Normally, for adult patients, a bottle (1 g mesalazine) as
Administration	a daily dose is injected through a rectal route. The dose
	may be decreased according to the age and symptoms.
4. NHI price	¥902.80. per bottle (1 g)
5. Packaging	100 ml x 7