

Long-acting selective H1 receptor antagonist for treatment of allergic diseases

Approval received for Claritin[®] Dry Syrup 1%

—Includes Pediatric Indication for Children Ages Three and Older—

Schering-Plough K.K. (Headquarters: Osaka, President: Masao Torii) and Shionogi & Co., Ltd. (Headquarters: Osaka, President: Motozo Shiono) received approval in Japan on October 19, 2007 for Claritin[®] Dry Syrup 1% (generic name: Loradatine dry syrup 1%), a long-acting selective H1 receptor antagonist the two companies have been jointly developing as a treatment for allergic diseases. Claritin[®] is an antihistamine for effectively treating allergic rhinitis (seasonal and chronic), urticaria, and itching associated with skin diseases (eczema, dermatitis, and pruritus cutaneous). Schering Plough Corporation of the United States created Claritin[®] and has marketed it for many years in more than 100 countries worldwide. Claritin[®] has been prescribed for over 400 million people. In Japan, Schering-Plough K.K. and Shionogi jointly market the prescription drugs Claritin[®] 10mg Tablet (launched September 2, 2002) and Claritin[®] RediTabs[®], 10mg Tablet (launched November 15, 2004), and intend to jointly market Claritin[®] Dry Syrup 1% as well once the National Health Insurance price has been set.

Easy for Young Children to Take

Claritin[®] Dry Syrup 1% has been approved for pediatric use for children ages three and older. The addition of sugar to the odorless and tasteless active ingredient makes it slightly sweet and easy to take. In general, it is administered in solution as loradatine in once-daily oral doses of 5mg (dry syrup: 0.5g) for children age three to seven and 10mg (dry syrup: 1.0g) for children ages seven and older after a meal. Claritin[®] has also been recognized for its effectiveness and safety for adults as a non-sedating antihistamine that has little effect on concentration or scholastic performance. Claritin[®] Dry Syrup 1% is not only safe and effective for children under the age of seven, but also offers the advantages of a single, easy-to-take dosage. It is therefore expected to make a significant contribution to the treatment of young children.

The Claritin Family: A Broad Array of Products

Schering-Plough and Shionogi have also received approval for the additional indication for children age seven and older for Claritin[®] 10mg Tablet and Claritin[®] RediTabs[®], 10mg Tablet.

With the addition of Claritin® Dry Syrup 1% for children ages 3 and older, the Claritin® family of products is the first lineup of antihistamines in Japan that is available in three dosage forms. It therefore offers a variety of choices to an exceptionally broad range of patient age groups.

For further information:

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Claritin® Dry Syrup 1% Product Overview

Product Name: Claritin® Dry Syrup 1%

Generic Name: Loratadine

Approval Date: October 19, 2007

NHI Drug Undetermined

Price:

Launch Date: Undetermined

Composition: Loratadine content: 10mg per gram

Inactive ingredients: Sugar, hydroxypropylcellulose, aqueous silicon dioxide

Formulation: White granules including powder

Indications: Allergic rhinitis, urticaria, and itching associated with skin diseases (eczema, dermatitis, and pruritus cutaneous)

Dosage and

Administration: Adults: Generally, one 10mg dose (dry syrup: 1g) as loratadine per day, administered orally in solution after a meal. The dose is adjusted based on age and symptoms.

Children: Generally, one 5mg dose (dry syrup: 0.5g) as loratadine per day for children from the age of three to seven, and one 10mg dose (dry syrup: 1 g) per day for children ages seven and older, administered orally in solution after a meal.

Packaging: Claritin® Dry Syrup 1%: 100g (0.5g x 150 packets)

Manufacturer and Marketer: Schering-Plough K.K.

Price: Undetermined

Product **1. Outstanding effectiveness in relieving allergic rhinitis, urticaria, and**

Characteristics: **itching associated with skin diseases**

- For the first time in Japan, effectiveness against chronic allergic rhinitis was confirmed three days after administration. Alleviation of nasal symptoms was significantly better than with a placebo.
- Symptoms of seasonal allergic rhinitis were significantly reduced compared with the placebo on the day of administration. Moreover, the effect continues until administration ceases. (Source: overseas data)
- For pediatric allergic rhinitis, lowered scores for the four nasal symptoms of sneezing, dripping, congestion and intranasal pruritus, which helps improve daily life.
- Demonstrated high rates of improvement of 89.1% for urticarial pruritus and 87.5% for the appearance of macula.
- Alleviated symptoms of pruritus associated with atopic dermatitis, including eczema, dermatitis, and pruritus cutaneous.
- Significantly reduced symptoms of pruritus associated with atopic dermatitis compared with the placebo. (Source: overseas data)
- Alleviated day- and night-time itching from pediatric atopic dermatitis from the day after administration began, and substantially lowered main pruritus scores.

2. Non-sedating

Little difference in the ability to drive compared with the placebo was observed during studies of the effects on driving. As a result, Claritin[®] has little effect on daily activities because it does not exhibit the same sedative effect as other antihistamines.

3. Sustained antihistamine action

Sustained action against wheal and erythema induced by histamines was observed during clinical trials. A single daily dosage offers excellent clinical effectiveness.

4. Easy to use and rapid action

- Single daily dosage ensures a high rate of dosing compliance.
- Acts quickly.