

October 19, 2007
Schering-Plough K.K.
Shionogi & Co., Ltd.

Additional Pediatric Indication Approved for Claritin[®]

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

Claritin[®] Tablet 10mg and Claritin[®] Reditabs[®], 10mg Tablet

—Additional Indication for Children Ages Seven and Older Approved—

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 the additional indication for children ages seven and older for Claritin[®] Tablet 10mg (generic name: Loradatine tablets) and for Claritin[®] Reditabs, 10mg Tablet (generic name: Loradatine oral instantly dispersing tablets), which are long-acting selective H1 receptor antagonists for the treatment of allergic diseases the two companies have been jointly developing.

Easy Dosing Expected to Enhance Compliance among Pediatric Patients Ages Seven and Older

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 more than 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). Claritin[®] RediTabs[®], 10mg Tablet disperses instantly on the tongue without water and can be taken quickly anywhere. This easy dosing is a particular merit among pediatric patients ages seven and older.

Non-Drowsy Claritin[®] Has Little Effect on Concentration or Scholastic Performance among School-Age Children

Just one dose of Claritin[®] is required daily, and this non-sedating antihistamine has little effect on concentration or scholastic performance. The same effectiveness and safety evident in use among adults has been confirmed for school-age patients. The recently approved additional indication expands the range of age groups for which Claritin[®] can serve as a helpful antihistamine for treating allergic diseases.

The Claritin Family: A Broad Array of Products

Schering-Plough and Shionogi have also received approval for the additional indication for children ages three and older for Claritin® Dry Syrup 1%. In tandem with approval for the additional indication for children ages seven and older for Claritin® 10mg Tablet and Claritin® RediTabs®, 10mg Tablet, 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:

Schering-Plough K.K.	Communications Department	Tokyo	Tel:03-6901-1212
			Fax:03-6901-1211
Shionogi & Co., Ltd.	Public Relations Unit	Osaka	Tel:06-6209-7885
			Fax:06-6229-9596
		Tokyo	Tel:03-3406-8164
			Fax:03-3406-8099

Claritin® Tablet 10mg Product Overview

Product Name: Claritin® Tablet 10mg

Generic Name: Loratadine

Approval Date: July 5, 2002 (Additional pediatric indication: October 19, 2007)

Composition: Loratadine content: 10mg per tablet

Inactive ingredients: Lactose monohydrate, corn starch, magnesium stearate

Formulation: Round white tablet with secant

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

Dosage and

Administration: Adults: Generally, one 10mg dose as loratadine taken orally once a day after a meal. The dose is adjusted based on age and symptoms.

Children ages seven and older: Generally, one 10mg dose as loratadine taken orally once a day after a meal.

Packaging:	100 tablets	10 tablets in PTP x 10
	420 tablets	14 tablets in PTP x 30
	500 tablets	10 tablets in PTP x 50
	1,000 tablets	10 tablets in PTP x 100
	300 tablets	Bulk

Manufacturer Schering-Plough K.K.

and Marketer:

Price: ¥132.80 per tablet

Product **1. Outstanding effectiveness in relieving allergic rhinitis, urticaria, and itching associated with skin diseases**

Characteristics:

- 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. Widely prescribed worldwide

As of May 2007, Claritin[®] (loratadine) was approved in 117 countries, and was approved for pediatric use in 35 of these countries.

5. Easy to use and rapid action

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

Claritin® Reditabs®, 10mg Tablet Product Overview

Product Name: Claritin® Reditabs®, 10mg Tablet

Generic Name: Loratadine

Approval Date: February 27, 2004 (Additional pediatric indication: October 19, 2007)

Composition: Loratadine content: 10mg per tablet

Inactive ingredients: Citric acid, gelatin, D-mannitol, flavor

Formulation: Round white tablet (instantly dissolves in mouth)

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

Dosage and

Administration: Adults: Generally, one 10mg dose as loratadine taken orally once a day after a meal. The dose is adjusted based on age and symptoms.

Children ages seven and older: Generally, one 10mg dose as loratadine taken orally once a day after a meal.

Packaging	50 tablets	10 tablets in blister x 10
	300 tablets	14 tablets in blister x 30

Manufacturer

and Marketer: Schering-Plough K.K.

Price: ¥136.70 per tablet

Product **2. Outstanding effectiveness in relieving allergic rhinitis, urticaria, and itching associated with skin diseases**

Characteristics:

- 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. Can be taken anywhere without water

Claritin[®] Reditabs[®] dissolve instantly in the mouth and can be taken anywhere without water.

5. Easy to use and rapid action

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