The pharmacokinetic profile of loratadine in children in the 6- to 12-year age group has been evaluated. In vitro studies have shown that loratadine is rapidly absorbed following oral administration, with peak plasma concentrations occurring within 1 to 3 hours. The plasma concentration profile of loratadine was comparable to that following administration of a 5 mg loratadine syrup, suggesting that the pediatric dosage form may be suitable for children aged 2 to 5 years. The mean elimination half-life of loratadine in this age group was 18.2 hours (range = 6.7 to 37 hours), which is longer than that observed in adults (15 hours). The pharmacokinetic profile of descarboethoxyloratadine, the primary inactive metabolite of loratadine, was also evaluated. The mean elimination half-life of descarboethoxyloratadine was 34.9 hours (range = 11 to 59 hours), which is also longer than that observed in adults (20 hours). The pharmacokinetic profile of loratadine was not substantially different from that observed in normal subjects, with the exception of the pediatric population. The pharmacokinetic profile of descarboethoxyloratadine was not substantially different from that observed in normal subjects.

Hepatic Impairment: In a single-rising dose study in which doses up to 160 mg (16 times the clinical dose) were studied, loratadine did not exhibit any clinically significant changes in pharmacokinetic parameters. The elimination half-lives for loratadine and descarboethoxyloratadine were 24 hours and 50 hours, respectively, in patients with severe hepatic impairment.

Renal Impairment: In patients with renal impairment, the pharmacokinetic profile of loratadine was not substantially different from that observed in normal subjects. However, the elimination half-life of descarboethoxyloratadine was increased in patients with renal impairment.

Special Populations: In a single-rising dose study in which doses up to 160 mg (16 times the clinical dose) were studied, loratadine did not exhibit any clinically significant changes in pharmacokinetic parameters. The elimination half-lives for loratadine and descarboethoxyloratadine were 24 hours and 50 hours, respectively, in patients with severe hepatic impairment.

In placebo-controlled trials, 10 mg once daily of CLARITIN Tablets was superior to placebo and similar to clemastine 1% ointment in the management of chronic idiopathic urticaria, as assessed by patient and observer global assessment of efficacy. In these studies, the mean percentage reduction in the number of urticaria plaques was 74% in patients treated with CLARITIN Tablets, 76% in patients treated with clemastine 1% ointment, and 54% in patients treated with placebo. The mean percentage reduction in the number of urticaria plaques was similar in patients treated with CLARITIN Tablets and clemastine 1% ointment, but less in patients treated with placebo. In a single-rising dose study in which doses up to 160 mg (16 times the clinical dose) were studied, loratadine did not exhibit any clinically significant changes in pharmacokinetic parameters. The elimination half-lives for loratadine and descarboethoxyloratadine were 24 hours and 50 hours, respectively, in patients with severe hepatic impairment.

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There was no evidence of animal teratogenicity in studies performed in rats and rabbits at oral doses up to and including 10 mg/kg/day. There were no overt signs of toxicity in rats administered CLARITIN REDITABS for up to 2 years at doses as high as 25 mg/kg/day. The no-effect level was determined to be 5 mg/kg/day (approximately 250 times the human maximum recommended daily oral dose on a mg/m² basis). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, CLARITIN should be used during pregnancy only if clearly needed.

CLARITIN Tablets:

CLARITIN Tablets are available in a number of strengths and package sizes: 10 mg tablets in bottles of 30 tablets (NDC 0085-0458-10) and 500 tablets (NDC 0085-0458-06). The tablets are also available in polyvinyl chloride blister packages of 30 tablets (three laminated foil pouches, each containing one blister card of 10 tablets) (NDC 0085-0458-04) and 500 tablets (NDC 0085-0458-05); and 10 x 10 tablet Unit Dose-Hospital Pack (NDC 0085-0458-04).

CLARITIN Syrup:

CLARITIN Syrup is available in amber glass bottles of 4 oz (118 mL) per bottle (NDC 0085-0458-02) and 8 oz (237 mL) per bottle (NDC 0085-0458-03).

CLARITIN REDITABS:

CLARITIN REDITABS (loratadine rapidly-disintegrating tablets) are available for manufacturing by Schering Corporation by Kenilworth, NJ 07033 USA under U.S. Patent Nos. 4,282,233 and 4,371,516.

CLARITIN REDITABS are white to off-white compressed tablets impressed with the product identification number R 19639873. They are manufactured for Schering Corporation by F. Hoffmann-La Roche Ltd., Switzerland and are distributed by Schering Corporation by Kenilworth, NJ 07033 USA. The active ingredient in CLARITIN REDITABS is loratadine, a histamine H1 receptor antagonist, which is rapidly, almost quantitatively, absorbed following oral administration and is 90% metabolized by the liver to a desethylated metabolite, descarboethoxyloratadine, and the remainder is excreted in the urine. CLARITIN REDITABS are rapidly disintegrating, allowed for 5 seconds upon opening individual tablet blister.

CLARITIN Syrup:

CLARITIN Syrup contains 1 mg loratadine per mL. It is a clear, colorless to light-yellow liquid. The excipients in CLARITIN Syrup are (w/v): water, sodium benzoate, citric acid monohydrate, aspartame, sodium saccharin, orange flavoring, and natural lemon-lime flavoring. The pH of CLARITIN Syrup is 2.5 to 3.5. The product is aseptically manufactured in a neutral product environment. CLARITIN Syrup is available in amber glass bottles of 4 oz (118 mL) per bottle (NDC 0085-0458-02) and 8 oz (237 mL) per bottle (NDC 0085-0458-03). The bottles are protected from light by clear, colorless to light-yellow caps.

CLARITIN 10

CLARITIN 10 is manufactured for Schering Corporation by F. Hoffmann-La Roche Ltd., Switzerland and is distributed by Schering Corporation by Kenilworth, NJ 07033 USA.

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