The study listed may include approved and nonapproved uses, formulations, or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this registry, healthcare professionals should consult prescribing information for the product approved in their country.

Title of Study:

An Open-Label, Randomized Study Comparing Efficacy and Safety of Desloratadine vs. Cetirizine in the Treatment of Chinese Patients With Seasonal Allergic Rhinitis (SAR) (Protocol No. P02904)

Studied Period:	**Phase of Development:** III
JULY 2002 to OCT 2002	

Objectives:

The overall objective of this study was to evaluate the efficacy and safety of treatment with Desloratadine vs. Cetirizine in Chinese patients with symptomatic seasonal allergic rhinitis (SAR).

Methodology:

Open-Label, randomized, active-controlled, parallel-groups comparison conducted in conformance with Good Clinical Practice.

Number of Patients (planned and analyzed):

130 subjects received randomized treatment assignment: 66 Desloratadine 5 mg, and 64 Cetirizine 10 mg

Diagnosis and Main Criteria for Inclusion:

Subjects with at least a two-year history of seasonal allergic rhinitis; the total SAR symptom score must be ≥5 (out of a possible 15) with a nasal congestion score of ≥2.

Duration of Treatment:

14 days

Test Product, Dose, and Mode of Administration:

Desloratadine 5 mg, taken orally in the morning

Reference Therapy, Dose, and Mode of Administration:

Cetirizine 10 mg, taken orally in the morning

Criteria for Evaluation:

Efficacy:

The primary efficacy analysis was based on the change of SAR symptom scores from baseline to the study endpoint. The primary null hypothesis was that Desloratadine 5 mg will result in the same reduction in the change of SAR symptom scores compared with Cetirizine 10 mg. The secondary efficacy analysis included the global therapeutic assessment of response and the change of each SAR symptom score.

Safety:

Treatment-emergent adverse events were summarized in terms of incidence rates, severity distributions, and drug relationship distributions. These summary statistics were produced for the individual AE and each body system category.

Statistical Methods:

The change from baseline in the SAR symptom scores was summarized and analyzed by t-test. Wilcoxon test was used if appropriate. The global therapeutic assessment of response was analyzed using Wilcoxon 2-Sample Test and the change of each SAR symptom score was also analyzed using unpaired t-test or Wilcoxon rank-sum test.

SUMMARY-CONCLUSIONS

EFFICACY RESULTS:

1. Desloratadine 5 mg was effective in SAR symptom relief.
2. Desloratadine 5 mg had an overall profile similar to Cetirizine 10 mg in SAR symptom relief.

SAFETY RESULTS:

1. Desloratadine 5 mg showed a favorable safety and tolerability profile, with a low incidence of adverse events.
2. Desloratadine 5 mg was well tolerated and had an overall profile similar to that of Cetirizine 10 mg.

CONCLUSION:

In general, Desloratadine 5 mg is both safe and effective in treating symptomatic seasonal allergic rhinitis in Chinese patients.

Date of the Report: NOV 2002