SYNOPSIS

**INN**: FEXOFENADINE

**Study number**: M016455T/3001

**Study title**: A multicenter, double-blind, randomized, placebo-controlled, parallel study to assess the safety and tolerability of fexofenadine HCl 15 mg in children with allergic rhinitis

**CSR date**: 13 April 2004

The study results and synopsis are supplied for informational purposes only.

Not all of the study results have necessarily been reviewed by the Regulatory Authorities.

The decision to prescribe and take a product should always be made on the basis of the most recent version of the product information and product package insert in the country of prescription.

PDF name: Fexofenadine – Study 28

EMA request May 2011 – Publication of result-related information on paediatric studies submitted under Article 45 of Regulation (EC) No 1901/2006 (‘Paediatric Regulation’)  August 2011
STUDY SYNOPSIS

**Study number**  M016455T/3001

**Title**
A multicenter, double-blind, randomized, placebo-controlled, parallel study to assess the safety and tolerability of fexofenadine HCl 15 mg in children with allergic rhinitis

**Investigator(s), study site(s)**
Multicenter study, 43 investigative sites in the United States
See Appendix A.2.1 of original Clinical Study Report K2002CLN0009

**Study duration and dates**
The first subject was enrolled on 13 December 2001 and the last subject completed the study on 24 May 2002.

**Objectives**

**Primary objective:** to compare the safety and tolerability of fexofenadine 15 mg BID to placebo in young children (≥ 6 months to <1 year of age and weighing ≤ 10.5 kg) with allergic rhinitis (AR).

**Secondary objective:** to characterize short-term (1-week) efficacy.

**Study design**
This was a multicenter, double-blind, randomized, placebo-controlled, parallel group, two-arm study for young children (≥ 6 months to <1 year of age and weighing ≤ 10.5 kg) with AR. Subjects aged ≥ 1 year to <2 years and weighing ≤ 10.5 kg with AR could also be enrolled. Subjects were treated with either fexofenadine 15 mg or placebo granulation powder sprinkled on an approved vehicle twice daily (BID) for a minimum of 7 days (a minimum of 14 doses). There were two scheduled visits: Entry and Randomization (Visit 1) and Final or Early Discontinuation (Visit 2).

**Population**
Subjects ≥ 6 months to <1 year of age weighing ≤ 10.5 kg with a diagnosis of allergic rhinitis as indicated by previous medical history, pattern, or suggestive physical findings (subjects ≥ 1 year and <2 years of age and weighing ≤ 10.5 kg were also allowed to participate). The subjects were either current candidates for antihistamine therapy or had tolerated a therapeutic course of an antihistamine in the past.

**Treatments**
Subjects were treated twice daily (BID) with either:
- Oral placebo granulation powder sprinkled on an approved vehicle, or
- Oral 15 mg fexofenadine granulation powder sprinkled on an approved vehicle.
Granulation powder was contained in matching capsules.

**Safety data**
The primary interest of this study was the safety performance of fexofenadine. Safety was evaluated based on adverse events, vital signs, 12-lead electrocardiograms (ECGs), and physical examinations.

**Efficacy data**
Efficacy was of secondary interest in this study. At Visit 2, the investigator made an overall assessment of study medication effectiveness taking into consideration AR symptoms assessments at Visit 1 and Visit 2 as well as changes in AR physical findings between baseline and end of study.

**Statistical procedures**
Summary descriptive statistics are provided; no formal inferential statistical analyses were planned or performed. Adverse events were coded using the Medical Dictionary for Regulatory Activities (MedDRA) Version 5.1.

**Interim analysis**
No interim analysis was performed.

**Results – Study subjects and conduct**
A total of 174 subjects (85 in the fexofenadine treatment group and 89 in the placebo treatment group) were randomized and treated with study medication at 43 study sites. The 6 months to <1 year age group was comprised of 122 randomized and treated subjects (58 fexofenadine, 64 placebo). The 1 year to <2 year age group was comprised of 52 randomized and treated subjects (27 fexofenadine, 25 placebo). Overall, there were more subjects in the placebo group (8/89, 9.0%) that withdrew before the planned end of the study as compared to the fexofenadine group (5/85, 5.9%). Duration of treatment and compliance with study medication (percentage of total doses ingested) was similar for both fexofenadine- and placebo-treated subjects. Approximately 45% of the subjects in both treatment groups reported concomitant medication use during the study.

In the 6 months to <1 year age group, the mean subject age was 8.8 months for fexofenadine-treated subjects and 8.4 months for placebo-treated subjects. In the 1 year to <2 year age group, mean subject age was 16.1 and 15.7 months for fexofenadine- and placebo-treated subjects, respectively. Body weight ranged from 6.4 kg to 10.5 kg for all subjects. There were no statistically significant differences between the two treatment groups at baseline for any of the demographic variables (all ages combined).

**Results – Safety**
Overall frequencies of treatment-emergent adverse events (TEAEs) are summarized in Table 1.
The system organ class with the highest incidence of TEAEs was gastrointestinal disorders. The most common TEAE was vomiting NOS, and was reported in 12 (14.1%) fexofenadine HCl subjects and 14 (15.7%) placebo subjects.

One subject (1.1%) had a serious TEAE, which was assessed as not related to study medication by the investigator. A subject treated with placebo experienced a severe respiratory syncytial virus infection that resulted in hospitalization.

TEAEs leading to discontinuation were reported in 3.5% (3/85) of subjects receiving fexofenadine HCl and 3.4% (3/89) of subjects receiving placebo. No specific TEAE or system organ class could be identified as a major reason for discontinuation.

No clinically relevant changes from baseline to endstudy were observed in either treatment group with respect to vital signs, ECGs, and physical examinations.

The recoding of adverse events data in MedDRA did not change the safety profile of fexofenadine HCl, and the nature of adverse events reported remain consistent with those reported in the original study report.

**Results – Efficacy**

The overall assessment of AR symptoms, as well as change from baseline, was comparable in both treatment groups at end of study. In the investigator’s assessment of the effectiveness of treatment with study drug, 61.0% (36/59) of subjects in the fexofenadine treatment group and 52.3% (34/65) of subjects in the placebo treatment group (subjects with baseline and endstudy AR symptoms assessments, all ages combined) experienced moderate to complete relief from the symptoms of AR.

**Conclusions**

Fexofenadine was well tolerated in this study. There were no meaningful differences in the incidence, pattern, or intensity of treatment-emergent adverse events for subjects of all ages, subjects 6 months to <1 year of age, and subjects 1 year to <2 years of age in the fexofenadine and placebo treatment groups. Based on the investigator’s assessment of study drug effectiveness in subjects with both baseline and endstudy AR symptoms assessments, short-term (1-week) treatment with fexofenadine or placebo resulted in at least moderate relief from the symptoms of AR for more than one-half of all evaluated subjects.

The recoding of adverse event data did not change the safety profile of fexofenadine HCl.