

ENCLOSURE 3

**Summary of the Well Controlled Studies in Pediatric
Patients using Allegra®**

Enclosure 3. Pediatric Studies

Allegra® in Adequate and Well Controlled Pediatric Studies

Allegra® (fexofenadine) has been studied in adequate and well-controlled studies in pediatric patients in seasonal allergic rhinitis.

Specifically, under NDA#20872, these pediatric study protocols were submitted and evaluated.

Pivotal Trials 0066 and 0077: Seasonal Allergic Rhinitis (SAR) in Pediatric Patients (BID Dosing)

Phase III, multi-center, double blind, randomized, placebo-controlled, parallel study comparing the efficacy and safety of three dosage strengths of fexofenadine HCl 15 mg, 30 mg, and 60 mg BID in pediatric patients (ages 6-11).

Primary objective: investigate safety and efficacy compared to placebo treatment in patients 6-11 years.

Secondary objective: characterize the population pharmacokinetics of fexofenadine BID in pediatric SAR patients.

Four parallel treatment arms:

2 weeks dosage regimen of fexofenadine 15mg/day QD

2 weeks dosage regimen of fexofenadine 30mg/day BID

2 weeks dosage regimen of fexofenadine 60mg/day QD

2 weeks dosage regimen of placebo

ITT Patients	Fexofenadine 15 mg N = 223	Fexofenadine 30 mg N = 208	Fexofenadine 60 mg N = 212	Total N = 643
Age, yr				
Mean + SD	9.14 ± 1.63	9.09 ± 1.51	9.04 ± 1.65	
Range Distribution	5 - 12	5 - 12	5 - 11	

Patient Demographics of All Pediatric Studies in NDA 20872 Combined (Clinical Pharmacology and Controlled Studies)

	Placebo N = 229	Fexofenadine N = 661	Total
Gender			
Male	139 (61%)	391 (61%)	530 (60%)
Female	90 (39%)	270 (49%)	360 (40%)
Age, yr			
Mean + SD	9.2 ± 1.6	9.1 ± 1.6	9.1 ± 1.6
Range Distribution	6 – 11	5 – 12	5 – 12
6 - <9	77 (34%)	217 (33%)	294 (33%)
9 - 12	152 (66%)	444 (67%)	596 (67%)
Weight (kg)			
Mean + SD	36.6 ± 11.1	35.3 ± 10.8	35.6 ± 10.9
Range	21 – 77.1	17.7 – 93	17.7 – 93
<15	0	0	0
15 - <30	76 (33%)	239 (36%)	315 (35%)
30 - <45	112 (49%)	321 (49%)	433 (49%)
≥ 45	41 (18%)	96 (15%)	137 (16%)