These results are supplied for informational purposes only.
Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company: sanofi-aventis	**ClinialTrials.gov Identifier:** NCT00741897
	Study Code: M016455C_4001
Generic drug name: Fexofenadine	**Date:** 26/Aug/2008

Title of the study:	A Monitored Release Study On The Efficacy And Safety of Fexofenadine (Telfast®) 30mg Pediatric Tablets On Filipino Children Aged 6 To 11 for The Relief of Perennial And Intermittent Allergic Rhinitis (M016455C/4001)		
Investigator(s):	None		
Study center(s):	48 doctors in the Philippines		
Publications (reference):	none		
Study period: Date first **patient** enrolled: 20-Mar-2002 Date last **patient** completed: 06-Dec-2003		**Phase of development:** Phase IV	
Objectives:	The objective of this study was to determine the safety and efficacy of Fexofenadine (Telfast®) 30mg pediatric tablets on Filipino children aged 6 to 11 for the relief of symptoms associated with perennial and intermittent allergic rhinitis.		
Methodology:	Open-label, multi-center, observational study		
Number of patients: 264	Planned: 264	Randomized: NA	Treated: 264
Evaluated:	Efficacy: n=264	Safety: n=264	
Diagnosis and criteria for inclusion:	Children aged 6 to 11 years who manifest allergic rhinitis symptoms such as sneezing, rhinorrhea, itchy nose/palate/throat and/or itchy/watery/red eyes		
Investigational product: Dose: Administration:	Fexofenadine 30mg One 30mg tablet once daily for two weeks		
Duration of treatment: 14 days		**Duration of observation:** 14 days	
Reference therapy: Dose: Administration:	Not applicable		
Criteria for evaluation:			
Efficacy: Or Pharmacodynamics:	Assessment of treatment based on relief of symptoms was recorded by both the physician and patient.		

Safety:	Adverse events reported by the patient/subject or noted by the investigator
Statistical methods:	Physician's and patient's assessments of efficacy were summarized using frequency and percentage. Demographic data was tabulated, as well as frequency and percentage of symptoms at each visit.
Summary:	The study population was divided into 52.3% male and 47.7% female, with a mean age of 8.66 years. 85.6% of them have been experiencing allergic rhinitis prior to enrollment, with 27.3% of them having the condition for <6 mos., 16.7% for 6-11 mos., and 14% for a year or more. Majority of the patients had no concomitant illnesses (80.7%), but there were cases of upper respiratory tract infection in 9.8% and bronchial asthma in 4.5 of them. Most of these were treated with amoxicillin (4.55%) and salbutamol (4.17%).Treatment with fexofenadine 30mg once daily for 2 weeks resulted in complete relief in 74.2% and marked relief in 24.6% of patients, according to assessments recorded by physicians. These results were similar to the assessments made by the patients themselves, showing complete relief of symptoms in 75.8% and marked relief in 22.7%. For both assessments, those showing only moderate and slight relief were minimal.
Safety results:	No adverse event was reported or observed in this study.
Date of report:	14-Mar-2008