



Clinical Study Summary

CT Registry ID#: NCT00152412		
Study No.: A00385		
<i>These results are supplied for informational purposes only. Prescribing decisions should be made based on the approved package insert.</i>		
Based on Clinical Study Report document reference code: RRCE04D2203		
Proprietary Drug Name Xyzal®	INN Levocetirizine	Therapeutic area and indication(s) Pediatric allergic rhinitis
Name of Sponsor/Company: UCB		
Title of Study: A 4 weeks open, multi-center study evaluating the safety of levocetirizine 1.25 mg b.i.d. given as 0.5 mg/mL oral solution in 2 to 6 year-old children suffering from allergic rhinitis.		
Investigator(s) (number only):	5	
Study Center(s) (number only):	4	
Length of Study:		Phase of Development: Phase II (therapeutic exploratory)
Date first patient enrolled:	23-Jun-2004	
Date last patient completed:	29-Dec-2004	
Abstract: The study objectives were to assess the safety (primary) and efficacy (exploratory) of levocetirizine (LCTZ) 1.25 mg twice daily given as 0.5 mg/mL oral solution in 2- to 6-year-old children suffering from allergic rhinitis over 4 weeks of treatment. An additional exploratory objective was to describe the serum concentration of LCTZ after 1, 3, and 6 hours following the last treatment intake. Safety was assessed by physical examination, including vital signs, adverse events (AEs), serious adverse events (SAEs), and hematology and biochemistry laboratory parameters. AEs were reported by subjects' parents/legally acceptable representative(s) on the self assessment Daily Record Card (DRC), which was also assessed by the Investigator. Two safety blood samples of 5 mL were collected for clinical laboratory tests at selection (Visit 1) and at the end of the treatment (Visit 4). The evaluation of efficacy was done by the analysis of the Total 4 Symptoms Score (T4SS: sum of the scores of the severity of sneezing, rhinorrhea, nasal pruritus, and ocular pruritus), and the individual symptom scores (T4SS symptoms and nasal congestion). Serum concentration levels of LCTZ were measured approximately 1 hour after the last treatment in 10 subjects, approximately 3 hours after the last treatment intake in another 10 subjects, and approximately 6 hours after the last treatment intake in yet another 10 subjects. Male or female children between 2 and 6 years of age, suffering from allergic rhinitis (perennial and/or seasonal), and symptomatic as attested by a DRC, were eligible. At the start of treatment (Visit 2), results of clinical laboratory tests, other than those related to the allergic rhinitis, had to be within the specified reference ranges and subjects had to have conformed to the washout periods for forbidden medications. Safety and efficacy parameters were analyzed descriptively. Drug concentrations were listed by subject.		
Publication Reference(s) based on the study: None		
Number of Patients:		
Planned, N:	30	
Enrolled, N:	30	
Completed, n (%):	29 (96.7)	
Number of Patients Withdrawn, n (%):	1 (3.3)	



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Withdrawn due to Adverse Events, n (%):	0
Withdrawn for Other Reasons ^a , n (%):	1 (3.3)
^a vacancies for a long time	
Demography:	
Gender (Females/Males):	15/15
Age (years), mean(SD):	4.55 (1.32)
Race, n (%):	Caucasian, 28 (93.3)
Safety Outcomes:	
- Summary of treatment emergent adverse events, deaths, other serious adverse events and certain other significant adverse events:	
Nineteen (63.3%) subjects had treatment emergent AEs (TE-AEs) but none were considered related to study medication. The most frequent AEs that occurred during treatment were related to respiratory infections; namely, bronchitis (5 subjects, 16.7%), pharyngitis (3 subjects, 10%), and upper respiratory tract infection (4 subjects, 13.3%). All other AEs occurred in only 1 or 2 subjects. There were no deaths, SAEs, or AEs leading to withdrawal. None of the changes in hematology or biochemistry laboratory parameters were considered clinically significant. No clinically relevant changes in vital signs were noted.	
Treatment Emergent AEs:	LCTZ (N=30)
Patients with at least one TEAE, n (%):	19 (63.3)
<i>Patients with TEAEs (by Primary System Organ Class)</i>	<i>n (%) [n considered drug-related by the Investigator]</i>
Eye Disorders	2 (6.7) [0]
Gastrointestinal Disorders	2 (6.7) [0]
General Disorders and Administration Site Conditions	2 (6.7) [0]
Infections and Infestations	19 (63.3) [0]
Nervous System Disorders ^a	1 (3.3) [0]
Psychiatric Disorders ^b	1 (3.3) [0]
Reproductive System and Breast Disorders	1 (3.3) [0]
Respiratory, Thoracic, and Mediastinal Disorders	7 (23.3) [0]
Skin and Subcutaneous Tissue Disorders	1 (3.3) [0]
^a headache	
^b insomnia	
Death, SAEs, and Other SAEs:	
Deaths, n (%):	0
Patients with SAEs, n (%):	0
Exploratory Efficacy Outcomes:	
There was a marked improvement in T4SS from baseline of -1.10 (95% CI [- 1.60, -0.60]) at the final visit. A decrease was evident in all individual scores (sneezing, nasal pruritus, rhinorrhea, ocular pruritus, and nasal congestion) over the 4 weeks of treatment.	
Change from baseline in T4SS (ITT Population)	LCTZ (N=30)
Mean (SD)	-1.10 (1.34)
Median	-1.02
Minimum, maximum	-4.2, 1.9
95% confidence interval	(-1.60, 0.60)