

764 Cetirizine 10mg is Statistically Superior to Loratadine 10mg and Placebo for the Relief of Worst Seasonal Allergy Symptom(s) in Children Ages 6-11 Years

K. Wagner¹, K. Franklin¹, X. Tian², Z. Jafry¹ ¹Johnson & Johnson Consumer Inc., ²Johnson & Johnson China Ltd.

Objective

The objective of this post hoc analysis was to evaluate the effect of 10mg daily on the most severe SAR symptoms experienced by children.

Methods

A 2-week, double blind, randomized study was identified in which children ages 6 - 11 years old were randomized to treatment with cetirizine 10mg, loratadine 10mg or placebo daily.

Subjects rated severity daily for sneezing, runny nose, itchy eyes, and watery eyes. The symptoms with the highest baseline score were predefined as the worst symptom(s). When multiple symptoms shared the same highest (worst) baseline score, the daily average of ratings was calculated to represent the post-baseline rating of subjects' worst symptom(s). Change from baseline in symptom severity was evaluated for children with any baseline severity ≥ 1 (0=none, 3=severe).

Results

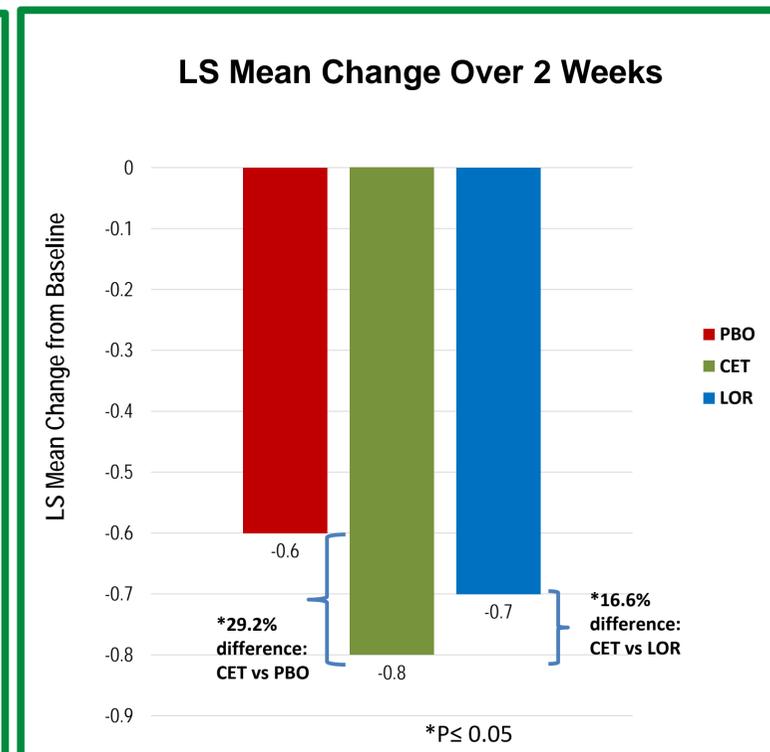
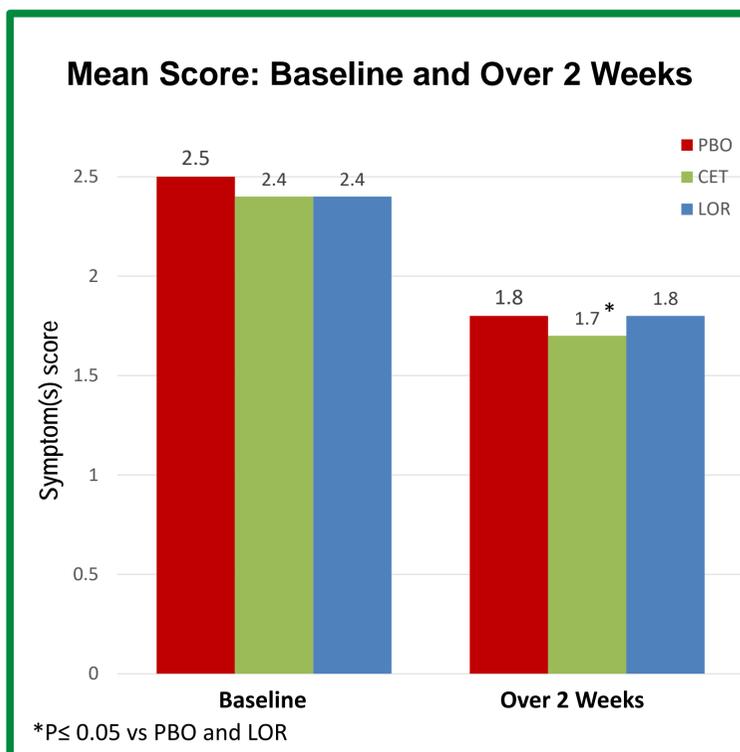
In this study, 228 children received cetirizine 10mg, 219 received loratadine 10mg, and 228 received placebo. Baseline mean worst symptom(s) score were not significantly different between the cetirizine, loratadine, and placebo groups (2.4, 2.4, and 2.5, respectively; $P=0.862$).

Over 2 weeks, the mean worst symptom(s) score was 1.7 for cetirizine 10mg, 1.8 for loratadine 10 mg, and 1.8 for placebo. The LS mean change from baseline worst symptom(s) score was -0.8 for cetirizine, -0.7 for loratadine, and -0.6 for placebo.

Cetirizine statistically relieved worst symptom(s) compared with loratadine ($P=0.040$, % difference =16.6%) and placebo ($P=0.001$, % difference =29.2%). Loratadine was not statistically different from placebo ($P=0.226$, %difference=10.8%).

Over 2 weeks, cetirizine was statistically superior to loratadine ($P=0.040$, %difference=16.6%) and placebo ($P=0.001$, %difference=29.2%) for the relief of worst seasonal allergic rhinitis symptom(s) in children ages 6 -11 years.

Relief of worst symptoms obtained with loratadine was not statistically different from placebo ($P=0.226$, %difference=10.8%).



Discussion

Post hoc analyses have demonstrated that cetirizine effectively relieves SAR symptoms with the highest baseline severity ratings (worst symptoms) in both children and adults. Cetirizine 10 mg has been shown to be effective for the relief of SAR worst symptom(s) in children ages 6-11 years of age¹ and subjects ≥ 12 years.² Cetirizine 5mg has also been shown to be effective for SAR worst symptom(s) in children ages 2-6 years of age.³

Symptom(s) Severity Score

	PBO	CET 10mg	LOR 10mg
Baseline			
N	228	228	219
Mean	2.5	2.4	2.4
Min, Max (SD)	1, 3 (0.50)	1, 3 (0.52)	1, 3 (0.49)
Over 2 Weeks			
N	228	228	219
Mean	1.8	1.7	1.8
Min, Max (SD)	0, 3 (0.67)	0, 3 (0.65)	0, 3 (0.61)

LS Mean Change from Baseline over 2 Weeks

	PBO	CET	LOR
LS Mean (SE)	-0.6 (0.05)	-0.8 (0.05)	-0.7 (0.05)
Between Treatment Comparisons			
	CET vs PBO	CET vs LOR	LOR vs PBO
P value	0.001	0.040	0.226
% Diff	29.2%	16.6%	10.8%

Conclusions

In children ages 6-11 years, cetirizine 10mg significantly improved the severity of worst SAR symptom(s), compared with loratadine and placebo. Loratadine 10mg was not significantly different from placebo for the relief of worst symptom(s).