

Appendix A

Evidence Tables

Evidence Table 1. Efficacy and Toxicity of Cetirizine vs Placebo

Ref Num/Author/Source Year	Design/Population		Purpose	Significant Factors	Groups/Outcomes				
					Groups	Cet	Placebo		
9 Rajaram S., et al. Indian Journal of Pharmacology. 1994	True Randomization Concealed Blinding Intent to Tx	NC NC Y Y	In the present study, the efficacy and tolerability of a single daily oral dose of cetirizine (10 mg) were assessed in patients with the symptoms of perennial allergic rhinitis and compared with oral astemizole (10 mg) and placebo treatments.	Antigen Source: Natural Exposure* Pollen Season: Not Considered Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of 2 wks and 4 wks Evaluator: Patient Placebo Lead-In: No	Groups N Dose (mg) Sig: Global Response + Percent Symptoms Baseline† Ave Symptoms Score STD Percent Reduction Sedation (%) All ADR (%)	Cet 17 10 qd 4wks 12 70.6% 9.3 4.3 42.7% 11.8% 17.6%	Placebo 16 4 qd 4wks 4 25.0% 9.6 7.5 0% 6.3%		
38 Falliers CJ., t al. Annals of Allergy. 1991	True Randomization Concealed Blinding Intent to Tx	NC NC Y Y	To compare the efficacy and safety of three once-daily dosing regimens of cetirizine with placebo in patients with documented seasonal allergic rhinitis.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: No Data for Evaluation: Average of 7 days Evaluator: Physician Placebo Lead-In: No	Groups N Dose (mg) Sig: Global Response Percent Symptoms Baseline Ave Symptoms Score STD Percent Reduction Sedation (%) All ADR (%)	Cet 104 10 bid 7d 51 49% 11.1 4.6 40.3% 25.0% 48.1%	Cet 106 10 qd 7d 51 48% 11.5 5.5 28.6% 22.6% 51.2%	Cet 102 5 qd 7d 37 36% 11.3 5.6 27.3% 8.8% 29.4%	Placebo 103 bid 7d 20 11.3 7.7 5.8% 28.2%
51 Mansmann HC., et al. Annal of Allergy 1992	True Randomization Concealed Blinding Intent to Tx	Y NC Y Y	In addition, because cetirizine is effective in single daily doses and causes few side effects, it is an excellent candidate for prolonged use. To investigate this, a double-blind, placebo controlled trial was undertaken to assess the safety and efficacy of cetirizine in alleviating the symptoms of perennial allergic rhinitis.	Antigen Source: Natural Exposure Pollen Season: No Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Average of 4 weeks Evaluator: Physician Placebo Lead-In: No	Groups N Dose (mg) Sig: Global Response Percent Symptoms Baseline Symptoms Reduction STD Percent Reduction Sedation (%) All ADR (%)	Cet 68 20 qd 4wks 37 54% 9.13 5.3 23.2% 22.5% 71.8%	Cet 72 10 qd 4 wks 35 49% 8.83 5.0 27.5% 15.3% 63.9%	Placebo 70 qd 4wks 19 27% 8.9 6.9 16.4% 50.7%	

Evidence Table 1. Cont.

Ref Num/Author/Source Year	Design/Population	Purpose	Significant Factors	Groups/Outcomes
59 Panayotopoulos SM., et al. Annals of Allergy. 1990	True Randomization NC Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: Adults N = 16	To correlate the therapeutic efficacy of cetirizine in allergic rhinoconjunctivitis of patients monosensitized to olive pollen with concentrations of this pollen in the atmosphere during one whole season	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: 40-200 particles/m ³ Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of 6 weekly scores Evaluator: Patient Placebo Lead-In: No	Groups Cet Placebo N 8 8 Dose (mg) 10 Sig: qd 4wks qd 4wks Global Response 6 1 Percent 75.0% 12.5% Symptoms Baseline Ave Symptoms Score 2.3 5.5 STD Percent Reduction 58.0%
80 Wasserman SI., et al. Clinical Therapeutics 1991	True Randomization NC Concealed N Blinding Y Intent to Tx N Seasonal Rhinitis Age: 18-79 years N = 88	This report describes a study of the efficacy and safety of cetirizine and patients with seasonal allergic rhinitis. In particular, we investigated the effect of several different dosing regimens on the drug's efficacy and safety.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: No Data for Evaluation: Average of 2 weeks Evaluator: Patient Placebo Lead-In: No	Groups Cet Cet Cet Placebo N 22 21 22 22 Dose (mg) 10 10 5 Sig: q AM 14d q HS 14d bid 14d bid 14d Symptoms Baseline 11.1 11.3 11.3 11.0 Ave Symptoms Score 3.3 4.0 4.5 5.7 STD Percent Reduction 42.1% 29.8% 21.1% Sedation (%) 14% 14% 29% 23% All ADR (%) 46% 38% 44% 46%
122 Day JH., et al. Annals of allergy, Asthma, & Immunology 1997	True Randomization NC Concealed NC Blinding Y Intent to Tx N Seasonal Rhinitis Age: 14-70 years N = 115	To compare the time to onset for clinically important relief of seasonal allergic rhinitis symptoms for each of the study groups. The secondary objective was to compare the relative efficacy of single doses of the aforementioned drugs in controlling the symptoms of seasonal allergic rhinitis.	Antigen Source: Environment Exposure Unit** Pollen Season: Induced Pollen Count: 5000 grains/m ³ Symptom Score: 5 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Average of 5 hours Evaluator: Patient Placebo Lead-In: No	Groups Cet Lor Placebo N 23 22 22 Dose (mg) 10 10 Sig: once once once Global Response 13 7 4 Percent 57.0% 32.0% 20.0% Sedation (%) 13% 0.0% 14% All ADR (%) 1.7% 0.09% 2.7%

Evidence Table 1. Cont.

Ref Num/Author/Source Year	Design/Population	Purpose	Significant Factors	Groups/Outcomes
130 Sabbah A., et al. Annals of Allergy, Asthma, & Immunology. 1999	True Randomization NC Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: >15 years N = 372	The aim of this European multicenter, randomized, double-blind study was to compare the efficacy of mizolastine 10 mg (n = 122), cetirizine 10 mg (n = 125), and placebo (n = 128) once daily for 28 days in patients with seasonal allergic rhinoconjunctivitis (SAR).	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Average of 7 days Evaluator: Physician Placebo Lead-In: No	Groups N Dose (mg) Sig: Symptoms Baseline Ave Symptoms Score STD Percent Reduction Sedation (%) All ADR (%) Cet 123 10 qd 28d 13.2 7.0 5.2 22.2% 9.9% 29.8% Placebo 124 qd 28d 13.1 9.0 5.9 4.0% 29.4%
133 Lockey RF., et al Annals of Allergy, Asthma, & Immunology. 1996	True Randomization NC Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: 12-70 years N = 283	The efficacy and safety of cetirizine 10 mg qd, terfenadine 60 mg bid, and placebo were compared in patients with seasonal allergic rhinitis.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: 23-1181 grains/m ³ Symptom Score: 10 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Average of 14 days Evaluator: Physician Placebo Lead-In: No	Groups N Dose (mg) Sig: Symptoms Baseline Ave Symptoms Score SEM Percent Reduction Sedation (%) All ADR (%) Cet 103 10 qd 14d 35.9 23.7 0.9 10.9% 11.7% 69.9% Placebo 105 qd 14d 36.2 26.6 1.1 2.9% 40.0%
189 Day JH., et al. Journal of Allergy & Clinical Immunology 1998	True Randomization Y Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: >16 years N = 202	To better characterize the efficacy and onset of action of cetirizine in a more controlled but clinically relevant setting, this agent was compared with loratadine and placebo in patients with symptomatic seasonal allergic rhinitis undergoing controlled pollen challenge in an environmental exposure unit.	Antigen Source: Environmental Exposure Unit Pollen Season: Yes Pollen Count: 3500 grains/m ³ Symptom Score: 5 to 8 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Average of 2 days Evaluator: Patient Placebo Lead-In: No	Groups N Dose (mg) Sig: Global Response Percent Symptoms Baseline Ave Symptoms Score STD Percent Reduction All ADR (%) Cet 67 10 qd 2d 41 60.9% 18.95 12.0 31.0% 30.0% Lor 67 10 qd 2d 34 50% 19.00 16.1 7.5% 37.5% Placebo 68 qd 2d 29 43.1% 19.76 17.4 37.0%

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Ref Num/Author/Source Year	Design/Population	Purpose	Significant Factors	Groups/Outcomes																																																		
200 Meltzer EO, et al Journal of Allergy & Clinical Immunology 1996	True Randomization Y Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: >18 years N = 279	The efficacy, duration and onset of action, and safety of cetirizine, 10 mg once daily, was compared with that of loratadine 10 mg once daily and placebo in a field study of patients with seasonal allergic rhinitis.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: 26-227/m ³ Symptom Score: 6 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Average of 2 days Evaluator: Patients Placebo Lead-In: No	<table border="1"> <thead> <tr> <th>Groups</th> <th>Cet</th> <th>Lor</th> <th>Placebo</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>93</td> <td>93</td> <td>93</td> </tr> <tr> <td>Dose (mg)</td> <td>10</td> <td>10</td> <td></td> </tr> <tr> <td>Sig:</td> <td>qd 2d</td> <td>qd 2d</td> <td>qd 2d</td> </tr> <tr> <td>Global Response</td> <td>67</td> <td>52</td> <td>54</td> </tr> <tr> <td>Percent</td> <td>73.6%</td> <td>56.5%</td> <td>59.3%</td> </tr> <tr> <td>Symptoms Baseline</td> <td>21.1</td> <td>20.5</td> <td>18.6</td> </tr> <tr> <td>Ave Symptoms Score</td> <td>11.2</td> <td>13.0</td> <td>12.6</td> </tr> <tr> <td>STD</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Percent Reduction</td> <td>11.1%</td> <td>-3.2%</td> <td></td> </tr> <tr> <td>Sedation (%)</td> <td>12.9%</td> <td>5.4%</td> <td>2.2%</td> </tr> <tr> <td>All ADR (%)</td> <td>30.1%</td> <td>36.7%</td> <td>33.5%</td> </tr> </tbody> </table>	Groups	Cet	Lor	Placebo	N	93	93	93	Dose (mg)	10	10		Sig:	qd 2d	qd 2d	qd 2d	Global Response	67	52	54	Percent	73.6%	56.5%	59.3%	Symptoms Baseline	21.1	20.5	18.6	Ave Symptoms Score	11.2	13.0	12.6	STD				Percent Reduction	11.1%	-3.2%		Sedation (%)	12.9%	5.4%	2.2%	All ADR (%)	30.1%	36.7%	33.5%		
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202 Howarth PH., et al. Journal of Allergy & Clinical Immunology. 1999	True Randomization NC Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: 12-65 years N = 821	A multicenter, double-blind, parallel group, placebo-controlled trial compared the efficacy and safety of fexofenadine HCl (120 and 180 mg administered once daily) and cetirizine (10 mg once daily) in the treatment of seasonal allergic rhinitis.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 5 pt Scale Include Nasal Congestion: No Data for Evaluation: Average of 14 days Evaluator: Patients Placebo Lead-in : Yes	<table border="1"> <thead> <tr> <th>Groups</th> <th>Fex</th> <th>Fex</th> <th>Cet</th> <th>Placebo</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>202</td> <td>211</td> <td>207</td> <td>201</td> </tr> <tr> <td>Dose (mg)</td> <td>180</td> <td>120</td> <td>10</td> <td></td> </tr> <tr> <td>Sig:</td> <td>qd 14d</td> <td>qd 14d</td> <td>qd 14d</td> <td>qd 14d</td> </tr> <tr> <td>Sym Baseline</td> <td>7.4</td> <td>7.2</td> <td>7.3</td> <td>7.3</td> </tr> <tr> <td>Ave Sym Score</td> <td>4.1</td> <td>4.2</td> <td>4.0</td> <td>5.4</td> </tr> <tr> <td>STD</td> <td>2.34</td> <td>2.34</td> <td>2.34</td> <td>2.34</td> </tr> <tr> <td>Percent Reduct</td> <td>24.1%</td> <td>22.2%</td> <td>25.9[†]</td> <td></td> </tr> <tr> <td>Sedation (%)</td> <td>3.0%</td> <td>3.0%</td> <td>6.0%</td> <td>3.0%</td> </tr> <tr> <td>All ADR (%)</td> <td>23.0%</td> <td>23.0%</td> <td>25.0%</td> <td>25.0%</td> </tr> </tbody> </table>	Groups	Fex	Fex	Cet	Placebo	N	202	211	207	201	Dose (mg)	180	120	10		Sig:	qd 14d	qd 14d	qd 14d	qd 14d	Sym Baseline	7.4	7.2	7.3	7.3	Ave Sym Score	4.1	4.2	4.0	5.4	STD	2.34	2.34	2.34	2.34	Percent Reduct	24.1%	22.2%	25.9 [†]		Sedation (%)	3.0%	3.0%	6.0%	3.0%	All ADR (%)	23.0%	23.0%	25.0%	25.0%
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Y= Yes, N=No, NC= Not Clear; Fex = Fexofenadine, Lor = Loratadine, Cet= Cetirizine; STD = Standard Deviation, SEM = Standard Error of the Mean

*All enpanelled patients had mild to moderate rhinitis at start of study and their symptoms were observed after being randomized to treatment or placebo groups.

**Mild to moderate rhinitis was induced and sustained in a controlled chamber and the patients' symptoms were documented after being randomized to treatment or placebo groups.

+The investigators and/or subjects measured the global response on a 4-8 point scale. Responders were subjects who had no symptoms or mild symptoms at a time of evaluation.

† The investigators and/or subjects measured the Symptoms on a 4-10 point scale for each of 5 to 8 symptoms on a daily bases. The reduction is the difference between the daily Symptoms Score after treatment and the Placebo.

Evidence Table 2. Efficacy and Toxicity of Loratadine vs Placebo

Ref Num/Author/Source Year	Design/Population	Purpose	Significant Factors	Groups/Outcomes		
21 Bedard PM., et al. Clinical Therapeutics 1992	True Randomization Y Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: 12-60 years N = 195	To evaluate the onset of action and efficacy of 10 mg of loratadine in the treatment of patients with seasonal allergic rhinitis.	Antigen Source: Natural Exposure* Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Day 3 Evaluator: Physician and Patient Placebo Lead-In: No	Groups N Dose (mg) Sig: Global Response+ Percent Symptoms Baseline † Symptoms Score STD Percent Reduction Sedation (%) All ADR (%)	Lor 91 10 qd 3d 46 50.0% 15.2 7.71 30.7% 2.0% 14.3%	Placebo 94 qd 3d 27 29.0% 14.9 10.1 1.0% 12.8%
27 Bruttman G., et al. Journal of Allergy & Clinical Immunology 1989	True Randomization Y Concealed NC Blinding NC Intent to Tx Y Seasonal Rhinitis Age: 18-45 years N = 70	To compare the efficacy and safety of a single oral daily dose of loratadine 40 mg, in patients with seasonal allergic rhinitis, with twice daily doses of terfenadine 60 mg or placebo.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: 2000-6500 grains/m ³ Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of day 3 and endpoint Evaluator: Physician Placebo Lead-In: No	Groups N Dose (mg) Sig: Global Response Percent Symptoms Baseline Ave Symptoms Score STD Percent Reduction Sedation (%) All ADR (%)	Lor 23 40 qd 14d 13 54.3% 9.2 5.22 49.8% 0% 0%	Placebo 23 qd 14d 1 2.0% 10.0 10.4 0% 13.0%
28 Bruttman G., et al. Journal of International Medical Research 1987	True Randomization Y Concealed NC Blinding Y Intent to Tx N Perennial Rhinitis Age: >12 years N = 239	To compare the efficacy and side effect profile of loratadine to that of terfenadine, and other non-sedating antihistamine, and placebo. We undertook a six-center study comparing loratadine (10mg qd) with terfenadine (60 mg bid) and placebo in patients with perennial allergic rhinitis.	Antigen Source: Natural Exposure Pollen Season: Not Considered Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of 4 weekly and endpoint Evaluator: Physician Placebo Lead-In: No	Groups N Dose (mg) Sig: Global Response Percent Symptoms Baseline Ave Symptoms Score STD Percent Reduction Sedation (%) All ADR (%)	Lor 73 10 qd 28d 45 61.6% 9.9 4.9 31.0% 2.6% 15.6%	Placebo 74 qd 28d 23 30.8% 10.3 7.1 2.6% 15.4%

Evidence Table 2. Cont.

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33 Del Carpio J., et al. Journal of allergy & Clinical Immunology 1989	True Randomization Y Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: >14 years N = 317	To compare the efficacy of a 10 mg qd dose of loratadine with efficacy of terfenadine, a widely used, non-sedating, antihistamine administered at 60 mg BID and placebo in the treatment of patients with seasonal allergic rhinitis.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of 2wks Evaluator: Physician Placebo Lead-In: No	<table border="0"> <tr> <td>Groups</td> <td>Lor</td> <td>Placebo</td> </tr> <tr> <td>N</td> <td>103</td> <td>101</td> </tr> <tr> <td>Dose (mg)</td> <td>10</td> <td></td> </tr> <tr> <td>Sig:</td> <td>qd 14d</td> <td>qd 14d</td> </tr> <tr> <td>Global Response</td> <td>60</td> <td>27</td> </tr> <tr> <td>Percent</td> <td>58.3%</td> <td>26.7%</td> </tr> <tr> <td>Symptoms Baseline</td> <td>12.7</td> <td>12.6</td> </tr> <tr> <td>Ave Symptoms Score</td> <td>6.9</td> <td>8.2</td> </tr> <tr> <td>STD</td> <td></td> <td></td> </tr> <tr> <td>Percent Reduction</td> <td>15.9%</td> <td></td> </tr> <tr> <td>Sedation (%)</td> <td>9.5%</td> <td>7.6%</td> </tr> <tr> <td>All ADR (%)</td> <td>26.7%</td> <td>20.9%</td> </tr> </table>	Groups	Lor	Placebo	N	103	101	Dose (mg)	10		Sig:	qd 14d	qd 14d	Global Response	60	27	Percent	58.3%	26.7%	Symptoms Baseline	12.7	12.6	Ave Symptoms Score	6.9	8.2	STD			Percent Reduction	15.9%		Sedation (%)	9.5%	7.6%	All ADR (%)	26.7%	20.9%
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35 Dockhorn RJ, et al. Annals of Allergy 1987	True Randomization Y Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: 18-45 years N = 330	To Evaluate and compare the efficacy and safety of loratadine 10 mg OD, clemastine 1 mg BID, and placebo when administered orally in the treatment of patients with seasonal allergic rhinitis.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of days 3,7,14 and endpoint Evaluator: Physician and Patient Placebo Lead-In: No	<table border="0"> <tr> <td>Groups</td> <td>Lor</td> <td>Placebo</td> </tr> <tr> <td>N</td> <td>108</td> <td>107</td> </tr> <tr> <td>Dose (mg)</td> <td>10</td> <td></td> </tr> <tr> <td>Sig:</td> <td>qd 14d</td> <td>qd 14d</td> </tr> <tr> <td>Global Response</td> <td>55</td> <td>47</td> </tr> <tr> <td>Percent</td> <td>50.5%</td> <td>43.5%</td> </tr> <tr> <td>Symptoms Baseline</td> <td>11.9</td> <td>11.7</td> </tr> <tr> <td>Ave Symptoms Score</td> <td>6.0</td> <td>8.9</td> </tr> <tr> <td>STD</td> <td></td> <td></td> </tr> <tr> <td>Percent Reduction</td> <td>32.7%</td> <td></td> </tr> <tr> <td>Sedation (%)</td> <td>6.3%</td> <td>4.5%</td> </tr> <tr> <td>All ADR (%)</td> <td>29.7%</td> <td>31.8%</td> </tr> </table>	Groups	Lor	Placebo	N	108	107	Dose (mg)	10		Sig:	qd 14d	qd 14d	Global Response	55	47	Percent	50.5%	43.5%	Symptoms Baseline	11.9	11.7	Ave Symptoms Score	6.0	8.9	STD			Percent Reduction	32.7%		Sedation (%)	6.3%	4.5%	All ADR (%)	29.7%	31.8%
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39 Frolund L., et al. Allergy 1990	True Randomization Y Concealed NC Blinding NC Intent to Tx Y Perennial Rhinitis Age: 18-65 years N = 155	To compare the efficacy and safety of loratadine 10 mg once daily, clemastine 1 mg twice daily, and placebo, in outpatients with perennial allergic rhinitis.	Antigen Source: Natural Exposure Pollen Season: Not considered Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of days 7, 14, and 21 Evaluator: Patient Placebo Lead-In: No	<table border="0"> <tr> <td>Groups</td> <td>Lor</td> <td>Placebo</td> </tr> <tr> <td>N</td> <td>48</td> <td>38</td> </tr> <tr> <td>Dose (mg)</td> <td>10</td> <td></td> </tr> <tr> <td>Sig:</td> <td>qd 21d</td> <td>qd 21d</td> </tr> <tr> <td>Symptoms Baseline</td> <td>6.4</td> <td>7.1</td> </tr> <tr> <td>Ave Symptoms Score</td> <td>3.4</td> <td>6.4</td> </tr> <tr> <td>STD</td> <td></td> <td></td> </tr> <tr> <td>Percent Reduction</td> <td>46.9%</td> <td></td> </tr> <tr> <td>Sedation (%)</td> <td>0%</td> <td>2.0%</td> </tr> <tr> <td>All ADR (%)</td> <td>15.1%</td> <td>49.0%</td> </tr> </table>	Groups	Lor	Placebo	N	48	38	Dose (mg)	10		Sig:	qd 21d	qd 21d	Symptoms Baseline	6.4	7.1	Ave Symptoms Score	3.4	6.4	STD			Percent Reduction	46.9%		Sedation (%)	0%	2.0%	All ADR (%)	15.1%	49.0%						
Groups	Lor	Placebo																																						
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Evidence Table 2. Cont.

Ref Num/Author/Source Year	Design/Population	Purpose	Significant Factors	Groups/Outcomes
42 Gutkowski A., et al Journal of Allergy & Clinical Immunology 1988	True Randomization Y Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: 14-62 years N = 280	To compare the efficacy and safety of loratadine, administered qd with terfenadine, administered bid and placebo in patients suffering from ragweed hay fever.	Antigen Source: Natural Exposure Pollen Season: Not considered Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Endpoint Evaluator: Physician Placebo Lead-In: No	Groups Lor Placebo N 91 88 Dose (mg) 40 Sig: qd 14d qd 14d Global Response 48 27 Percent 52.7% 32.5% Symptoms Baseline 13.8 14.1 Ave Symptoms Score 7.7 10.0 STD Percent Reduction 23.0%
44 Horak F., et al. Arzneimittel-Forschung 1988	True Randomization Y Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: 12-70 years N = 275	To further evaluate the efficacy and safety of loratadine. In this 14 day study, loratadine 10 mg once daily was compared to terfenadine 60 mg twice daily and placebo as oral therapy for outpatients with seasonal allergic rhinitis.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of day 3 and endpoint Evaluator: Physician Placebo Lead-In: No	Groups Lor Placebo N 87 80 Dose (mg) 10 Sig: qd 14d qd 14d Global Response 58 13 Percent 67% 16% Symptoms Baseline 13.4 13.5 Ave Symptoms Score 6.8 14.0 STD Percent Reduction 51.4% Sedation (%) 4.4% 7.1% All ADR (%) 6.7% 9.4%
57 Oei HD Annals of Allergy 1988	True Randomization Y Concealed NC Blinding Y Intent to Tx N Seasonal Rhinitis Age: 25 ± 10 years N = 65	To compare the time of onset of action and the clinical effectiveness of loratadine and astemizole, both given in a dose of 10 mg once a day for 2 weeks.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of day 3 and endpoint Evaluator: Physician Placebo Lead-In: No	Groups Lor Placebo N 22 21 Dose (mg) 10 Sig: qd 14d qd 14d Global Response 11 6 Percent 51.5% 28.5% Symptoms Baseline 12.1 13.6 Ave Symptoms Score 5.3 8.1 STD Percent Reduction 34.6% Sedation (%) 0% 4.8% All ADR (%) 18.2% 42.9%

Evidence Table 2. Cont.

Ref Num/Author/Source Year	Design/Population	Purpose	Significant Factors	Groups/Outcomes
74 Skassa-Brociek W., et al Journal of Allergy & Clinical Immunology 1988	True Randomization NC Concealed NC Blinding Y Intent to Tx N Seasonal Rhinitis Age: 14-58 years N = 69	A double-blind, controlled study compared the safety and efficacy of a lower dosage of loratadine (10 mg qd) with mequitazine (5mg bid) and placebo in the treatment of pollen induced seasonal rhinitis	Antigen Source: Natural Exposure Pollen Season: Not Considered Pollen Count: 15-65/m ³ Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of day 3 and endpoint Evaluator: Physician Placebo Lead-In: No	Groups Lor Placebo N 22 24 Dose (mg) 10 Sig: qd 14d qd 14d Global Response 8 0 Percent 36.4% 0% Symptoms Baseline 10.4 11.6 Ave Symptoms Score 4.9 7.7 STD Percent Reduction 36.4% Sedation (%) 4.6% 4.2% All ADR (%) 9.1% 37.5%
113 Dolovich J., et al Annals of Allergy 1994	True Randomization NC Concealed N Blinding N Intent to Tx N Seasonal Rhinitis Age: 17-60 years N = 118	A randomized, placebo-controlled study of the efficacy and safety of loratadine (10mg once daily) in the prophylactic treatment of seasonal allergic rhinitis was therefore conducted.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of day 3 and endpoint Evaluator: Physician Placebo Lead-In: No	Groups Lor Placebo N 58 60 Dose (mg) 10 Sig: qd 42d qd 42d Global Response 38 29 Percent 65% 49% Symptoms Baseline <2 <2 Ave Symptoms Score 3.2 3.47 STD Percent Reduction 7.8% Sedation (%) 3.4% 1.7% All ADR (%) 30.5% 28.3%
122 Day JH., et al. Annals of allergy, Asthma, & Immunology 1997	True Randomization NC Concealed NC Blinding Y Intent to Tx N Seasonal Rhinitis Age: 14-70 years N = 115	To compare the time to onset for clinically important relief of seasonal allergic rhinitis symptoms for each of the study groups. The secondary objective was to compare the relative efficacy of single doses of the aforementioned drugs in controlling the symptoms of seasonal allergic rhinitis.	Antigen Source: Environment Exposure Unit** Pollen Season: Induced Pollen Count: 5000 grains/m ³ Symptom Score: 5 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Average of 5 hours Evaluator: Patient Placebo Lead-In: No	Groups Cet Lor Placebo N 23 22 22 Dose (mg) 10 10 Sig: once once once Global Response 13 7 4 Percent 57.0% 32.0% 20.0% Sedation (%) 13% 0.0% 14% All ADR (%) 1.7% 0.09% 2.7%

Evidence Table 2. Cont.

Ref Num/Author/Source Year	Design/Population	Purpose	Significant Factors	Groups/Outcomes																																																
189 Day JH., et al. Journal of allergy & Clinical Immunology 1998	True Randomization Y Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age:>16 years N = 202	To better characterize the efficacy and onset of action of cetirizine in a more controlled but clinically relevant setting, this agent was compared with loratadine and placebo in patients with symptomatic seasonal allergic rhinitis undergoing controlled pollen challenge in an environmental exposure unit.	Antigen Source: Environmental Exposure Unit Pollen Season: Induced Pollen Count: 3500 grains/m ³ Symptom Score: 5 to 8 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Average of 2 days Evaluator: Patient Placebo Lead-In: No	<table border="1"> <thead> <tr> <th>Groups</th> <th>Cet</th> <th>Lor</th> <th>Placebo</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>67</td> <td>67</td> <td>68</td> </tr> <tr> <td>Dose (mg)</td> <td>10</td> <td>10</td> <td>qd 2d</td> </tr> <tr> <td>Sig:</td> <td>qd 2d</td> <td>qd 2d</td> <td>qd 2d</td> </tr> <tr> <td>Global Response</td> <td>41</td> <td>34</td> <td>29</td> </tr> <tr> <td>Percent</td> <td>60.9%</td> <td>50%</td> <td>43.1%</td> </tr> <tr> <td>Symptoms Baseline</td> <td>18.95</td> <td>19.00</td> <td>19.76</td> </tr> <tr> <td>Ave Symptoms Score</td> <td>12.0</td> <td>16.1</td> <td>17.4</td> </tr> <tr> <td>STD</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Percent Reduction</td> <td>31.0%</td> <td>7.5%</td> <td></td> </tr> <tr> <td>All ADR (%)</td> <td>30.0%</td> <td>37.5%</td> <td>37.0%</td> </tr> </tbody> </table>	Groups	Cet	Lor	Placebo	N	67	67	68	Dose (mg)	10	10	qd 2d	Sig:	qd 2d	qd 2d	qd 2d	Global Response	41	34	29	Percent	60.9%	50%	43.1%	Symptoms Baseline	18.95	19.00	19.76	Ave Symptoms Score	12.0	16.1	17.4	STD				Percent Reduction	31.0%	7.5%		All ADR (%)	30.0%	37.5%	37.0%				
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200 Meltzer EO, et al Journal of Allergy & Clinical Immunology 1996	True Randomization Y Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: >18 years N = 279	The efficacy, duration and onset of action, and safety of cetirizine, 10 mg once daily, was compared with that of loratadine 10 mg once daily and placebo in a field study of patients with seasonal allergic rhinitis.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: 26-227/m ³ Symptom Score: 6 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Average of 2 days Evaluator: Patients Placebo Lead-In: No	<table border="1"> <thead> <tr> <th>Groups</th> <th>Cet</th> <th>Lor</th> <th>Placebo</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>93</td> <td>93</td> <td>93</td> </tr> <tr> <td>Dose (mg)</td> <td>10</td> <td>10</td> <td>qd 2d</td> </tr> <tr> <td>Sig:</td> <td>qd 2d</td> <td>qd 2d</td> <td>qd 2d</td> </tr> <tr> <td>Global Response</td> <td>67</td> <td>52</td> <td>54</td> </tr> <tr> <td>Percent</td> <td>73.6%</td> <td>56.5%</td> <td>59.3%</td> </tr> <tr> <td>Symptoms Baseline</td> <td>21.1</td> <td>20.5</td> <td>18.6</td> </tr> <tr> <td>Ave Symptoms Score</td> <td>11.2</td> <td>13.0</td> <td>12.6</td> </tr> <tr> <td>STD</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Percent Reduction</td> <td>11.1%</td> <td>-3.2%</td> <td></td> </tr> <tr> <td>Sedation (%)</td> <td>12.9%</td> <td>5.4%</td> <td>2.2%</td> </tr> <tr> <td>All ADR (%)</td> <td>30.1%</td> <td>36.7%</td> <td>33.5%</td> </tr> </tbody> </table>	Groups	Cet	Lor	Placebo	N	93	93	93	Dose (mg)	10	10	qd 2d	Sig:	qd 2d	qd 2d	qd 2d	Global Response	67	52	54	Percent	73.6%	56.5%	59.3%	Symptoms Baseline	21.1	20.5	18.6	Ave Symptoms Score	11.2	13.0	12.6	STD				Percent Reduction	11.1%	-3.2%		Sedation (%)	12.9%	5.4%	2.2%	All ADR (%)	30.1%	36.7%	33.5%
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Y= Yes, N=No, NC= Not Clear; Fex = Fexofenadine, Lor = Loratadine, Cet= Cetirizine; STD = Standard Deviation, SEM = Standard Error of the Mean

*All enpanelled patients had mild to moderate rhinitis at start of study and their symptoms were observed after being randomized to treatment or placebo groups.

**Mild to moderate rhinitis was induced and sustained in a controlled chamber and the patients' symptoms were documented after being randomized to treatment or placebo groups.

+The investigators and/or subjects measured the global response on a 4-8 point scale. Responders were subjects who had no symptoms or mild symptoms at a time of evaluation.

† The investigators and/or subjects measured the Symptoms on a 4-10 point scale for each of 5 to 8 symptoms on a daily bases. The reduction is the difference between the daily Symptoms Score after treatment and the Placebo.

Evidence Table 3. Efficacy and Toxicity of Fexofenadine vs Placebo

Ref Num/Author/Source Year	Design/Population	Purpose	Significant Factors	Groups/Outcomes																																																		
102 Casale TB., et al. Allergy & Asthma Proceedings 1999	True Randomization NC Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: 12-65 years N = 861	To confirm the efficacy and safety of once-daily dosing of fexofenadine HCl (120 mg and 180 mg QD) compared with placebo in the treatment of autumn SAR.	Antigen Source: Natural Exposure* Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 5 pt Scale Include Nasal Congestion: No Data for Evaluation: Ave of 14 days Evaluator: Patient Placebo Lead-In: Yes	<table border="1"> <thead> <tr> <th>Groups</th> <th>Fex</th> <th>Fex</th> <th>Placebo</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>282</td> <td>287</td> <td>292</td> </tr> <tr> <td>Dose (mg)</td> <td>180</td> <td>120</td> <td>qd 14d</td> </tr> <tr> <td>Sig:</td> <td>qd 14d</td> <td>qd 14d</td> <td>qd 14d</td> </tr> <tr> <td>Symptoms Baseline †</td> <td>7.7</td> <td>7.7</td> <td>7.6</td> </tr> <tr> <td>Ave Symptoms Score</td> <td>6.3</td> <td>6.4</td> <td>6.9</td> </tr> <tr> <td>SEM</td> <td>0.1</td> <td>0.1</td> <td>0.1</td> </tr> <tr> <td>Percent Reduction</td> <td>8.7%</td> <td>7.2%</td> <td></td> </tr> <tr> <td>Sedation (%)</td> <td>Not Reported</td> <td></td> <td></td> </tr> <tr> <td>All ADR (%)</td> <td>30.4%</td> <td>30.0%</td> <td>30.0%</td> </tr> </tbody> </table>	Groups	Fex	Fex	Placebo	N	282	287	292	Dose (mg)	180	120	qd 14d	Sig:	qd 14d	qd 14d	qd 14d	Symptoms Baseline †	7.7	7.7	7.6	Ave Symptoms Score	6.3	6.4	6.9	SEM	0.1	0.1	0.1	Percent Reduction	8.7%	7.2%		Sedation (%)	Not Reported			All ADR (%)	30.4%	30.0%	30.0%										
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103 Bronsky EA., et al. Allergy & Asthma Proceedings 1998	True Randomization NC Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: 12-65 years N = 589	To evaluate the clinical efficacy and safety of fexofenadine HCl (40, 60, and 120 mg bid) compared with placebo in the treatment of fall SAR.	Antigen Source: Natural Exposure Pollen Season: Not Considered Pollen Count: Not Collected Symptom Score: 5 pt Scale Include Nasal Congestion: No Data for Evaluation: Ave of 14 days Evaluator: Patient Placebo Lead-In: Yes	<table border="1"> <thead> <tr> <th>Groups</th> <th>Fex</th> <th>Fex</th> <th>Fex</th> <th>Placebo</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>135</td> <td>138</td> <td>135</td> <td>137</td> </tr> <tr> <td>Dose (mg)</td> <td>120</td> <td>60</td> <td>40</td> <td></td> </tr> <tr> <td>Sig:</td> <td>bid 14d</td> <td>bid 14d</td> <td>bid 14d</td> <td>bid 14d</td> </tr> <tr> <td>Symptoms Baseline</td> <td>8.4</td> <td>8.6</td> <td>8.6</td> <td>8.6</td> </tr> <tr> <td>Ave Symptoms Score</td> <td>6.3</td> <td>6.8</td> <td>6.8</td> <td>7.4</td> </tr> <tr> <td>SEM</td> <td>0.2</td> <td>0.2</td> <td>0.2</td> <td>0.2</td> </tr> <tr> <td>Percent Reduction</td> <td>15.7%</td> <td>8.1%</td> <td>8.1%</td> <td></td> </tr> <tr> <td>Sedation (%)</td> <td>Not Reported</td> <td></td> <td></td> <td></td> </tr> <tr> <td>All ADR (%)</td> <td>13.5%</td> <td>13.5%</td> <td>13.5%</td> <td>13.6%</td> </tr> </tbody> </table>	Groups	Fex	Fex	Fex	Placebo	N	135	138	135	137	Dose (mg)	120	60	40		Sig:	bid 14d	bid 14d	bid 14d	bid 14d	Symptoms Baseline	8.4	8.6	8.6	8.6	Ave Symptoms Score	6.3	6.8	6.8	7.4	SEM	0.2	0.2	0.2	0.2	Percent Reduction	15.7%	8.1%	8.1%		Sedation (%)	Not Reported				All ADR (%)	13.5%	13.5%	13.5%	13.6%
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124 Bernstein D., et al. Annals of Allergy, Asthma, & Immunology.. 1997	True Randomization NC Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: 12-65 years N = 575	To evaluate the efficacy and safety of a range of fexofenadine HCl doses (60, 120, and 240 mg bid) compared with placebo for the treatment of seasonal allergic rhinitis due to ragweed pollen exposure.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 5 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of 14 days Evaluator: Patient Placebo Lead-In: Yes	<table border="1"> <thead> <tr> <th>Groups</th> <th>Fex</th> <th>Fex</th> <th>Fex</th> <th>Placebo</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>144</td> <td>144</td> <td>141</td> <td>141</td> </tr> <tr> <td>Dose (mg)</td> <td>240</td> <td>120</td> <td>60</td> <td></td> </tr> <tr> <td>Sig:</td> <td>bid 14d</td> <td>bid 14d</td> <td>bid 14d</td> <td>bid 14d</td> </tr> <tr> <td>Symptoms Baseline</td> <td>8.8</td> <td>9.0</td> <td>8.8</td> <td>8.9</td> </tr> <tr> <td>Ave Symptoms Score</td> <td>6.2</td> <td>6.6</td> <td>6.2</td> <td>7.4</td> </tr> <tr> <td>SEM</td> <td>0.2</td> <td>0.2</td> <td>0.2</td> <td>0.2</td> </tr> <tr> <td>Percent Reduction</td> <td>16.2%</td> <td>10.8%</td> <td>16.2%</td> <td></td> </tr> <tr> <td>Sedation (%)</td> <td>Not Reported</td> <td></td> <td></td> <td></td> </tr> <tr> <td>All ADR (%)</td> <td>11.7%</td> <td>6.9%</td> <td>14.2%</td> <td>9.2%</td> </tr> </tbody> </table>	Groups	Fex	Fex	Fex	Placebo	N	144	144	141	141	Dose (mg)	240	120	60		Sig:	bid 14d	bid 14d	bid 14d	bid 14d	Symptoms Baseline	8.8	9.0	8.8	8.9	Ave Symptoms Score	6.2	6.6	6.2	7.4	SEM	0.2	0.2	0.2	0.2	Percent Reduction	16.2%	10.8%	16.2%		Sedation (%)	Not Reported				All ADR (%)	11.7%	6.9%	14.2%	9.2%
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202 Howarth PH., et al. Journal of Allergy & Clinical Immunology. 1999	True Randomization NC Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: 12-65 years N = 821	A multicenter, double-blind, parallel group, placebo-controlled trial compared the efficacy and safety of fexofenadine HCl (120 and 180 mg administered once daily) and cetirizine (10 mg once daily) in the treatment of seasonal allergic rhinitis.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 5 pt Scale Include Nasal Congestion: No Data for Evaluation: Average of 14 days Evaluator: Patients Placebo Lead-in : Yes	<table border="1"> <thead> <tr> <th>Groups</th> <th>Fex</th> <th>Fex</th> <th>Cet</th> <th>Placebo</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>202</td> <td>211</td> <td>207</td> <td>201</td> </tr> <tr> <td>Dose (mg)</td> <td>180</td> <td>120</td> <td>10</td> <td></td> </tr> <tr> <td>Sig:</td> <td>qd 14d</td> <td>qd 14d</td> <td>qd 14d</td> <td>qd 14d</td> </tr> <tr> <td>Sym Baseline</td> <td>7.4</td> <td>7.2</td> <td>7.3</td> <td>7.3</td> </tr> <tr> <td>Ave Sym Score</td> <td>4.1</td> <td>4.2</td> <td>4.0</td> <td>5.4</td> </tr> <tr> <td>STD</td> <td>2.34</td> <td>2.34</td> <td>2.34</td> <td>2.34</td> </tr> <tr> <td>Percent Reduct</td> <td>24.1%</td> <td>22.2%</td> <td>25.9%</td> <td></td> </tr> <tr> <td>Sedation (%)</td> <td>3.0%</td> <td>3.0%</td> <td>6.0%</td> <td>3.0%</td> </tr> <tr> <td>All ADR (%)</td> <td>23.0%</td> <td>23.0%</td> <td>25.0%</td> <td>25.0%</td> </tr> </tbody> </table>	Groups	Fex	Fex	Cet	Placebo	N	202	211	207	201	Dose (mg)	180	120	10		Sig:	qd 14d	qd 14d	qd 14d	qd 14d	Sym Baseline	7.4	7.2	7.3	7.3	Ave Sym Score	4.1	4.2	4.0	5.4	STD	2.34	2.34	2.34	2.34	Percent Reduct	24.1%	22.2%	25.9%		Sedation (%)	3.0%	3.0%	6.0%	3.0%	All ADR (%)	23.0%	23.0%	25.0%	25.0%
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Y= Yes, N=No, NC= Not Clear; Fex = Fexofenadine, Lor = Loratadine, Cet= Cetirizine; STD = Standard Deviation, SEM = Standard Error of the Mean

*All enpanelled patients had mild to moderate rhinitis at start of study and their symptoms were observed after being randomized to treatment or placebo groups.

**Mild to moderate rhinitis was induced and sustained in a controlled chamber and the patients' symptoms were documented after being randomized to treatment or placebo groups.

+The investigators and/or subjects measured the global response on a 4-8 point scale. Responders were subjects who had no symptoms or mild symptoms at a time of evaluation.

† The investigators and/or subjects measured the Symptoms on a 4-10 point scale for each of 5 to 8 symptoms on a daily bases. The reduction is the difference between the daily Symptoms Score after treatment and the Placebo.

Evidence Table 4. Efficacy and Toxicity of Chlorpheniramine vs Terfenadine

Ref Num/Author/Source Year	Design/Population	Purpose	Significant Factors	Groups/Outcomes																																								
111 Brandon ML., et al. Annals of Allergy 1980	True Randomization NC Concealed NC Blinding Y Intent to Tx N Seasonal Rhinitis Age: Adults N = 120	To compare the efficacy and safety of chlorpheniramine vs terfenadine and placebo.	Antigen Source: Natural Exposure* Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 5 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of 3-4 days Evaluator: Physician Placebo Lead-In: No	<table border="1"> <thead> <tr> <th>Groups</th> <th>Ter</th> <th>Chlor</th> <th>Placebo</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>40</td> <td>40</td> <td>40</td> </tr> <tr> <td>Dose (mg)</td> <td>30</td> <td>4</td> <td></td> </tr> <tr> <td>Sig:</td> <td>qid</td> <td>qid</td> <td>qid</td> </tr> <tr> <td>Global Response +</td> <td>21</td> <td>27</td> <td>16</td> </tr> <tr> <td>Percent</td> <td>52.5%</td> <td>67.5%</td> <td>40.0%</td> </tr> <tr> <td>Sedation (%)</td> <td>10%</td> <td>23%</td> <td>10%</td> </tr> <tr> <td>All ADR (%)</td> <td>33%</td> <td>40%</td> <td>35%</td> </tr> </tbody> </table>	Groups	Ter	Chlor	Placebo	N	40	40	40	Dose (mg)	30	4		Sig:	qid	qid	qid	Global Response +	21	27	16	Percent	52.5%	67.5%	40.0%	Sedation (%)	10%	23%	10%	All ADR (%)	33%	40%	35%								
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111 Brandon ML., et al. Annals of Allergy 1980	True Randomization NC Concealed NC Blinding Y Intent to Tx N Seasonal Rhinitis Age: Adults N = 122	To compare the efficacy and safety of chlorpheniramine vs terfenadine and placebo.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 5 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of 2 days Evaluator: Physician Placebo Lead-In: No	<table border="1"> <thead> <tr> <th>Groups</th> <th>Ter</th> <th>Chlor</th> <th>Placebo</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>42</td> <td>41</td> <td>39</td> </tr> <tr> <td>Dose (mg)</td> <td>100</td> <td>4</td> <td></td> </tr> <tr> <td>Sig:</td> <td>qid</td> <td>qid</td> <td>qid</td> </tr> <tr> <td>Global Response</td> <td>21</td> <td>25</td> <td>21</td> </tr> <tr> <td>Percent</td> <td>50.0%</td> <td>61.0%</td> <td>54.0%</td> </tr> <tr> <td>Sedation (%)</td> <td>14%</td> <td>15%</td> <td>8%</td> </tr> <tr> <td>All ADR (%)</td> <td>24%</td> <td>34%</td> <td>13%</td> </tr> </tbody> </table>	Groups	Ter	Chlor	Placebo	N	42	41	39	Dose (mg)	100	4		Sig:	qid	qid	qid	Global Response	21	25	21	Percent	50.0%	61.0%	54.0%	Sedation (%)	14%	15%	8%	All ADR (%)	24%	34%	13%								
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111 Brandon ML., et al. Annals of Allergy 1980	True Randomization NC Concealed NC Blinding Y Intent to Tx N Seasonal Rhinitis Age: Adults N = 137	To compare the efficacy and safety of chlorpheniramine vs terfenadine and placebo.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 5 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of 2 days Evaluator: Physician Placebo Lead-In: No	<table border="1"> <thead> <tr> <th>Groups</th> <th>Ter</th> <th>Ter</th> <th>Chlor</th> <th>Placebo</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>36</td> <td>31</td> <td>34</td> <td>36</td> </tr> <tr> <td>Dose (mg)</td> <td>200</td> <td>20</td> <td>4</td> <td></td> </tr> <tr> <td>Sig:</td> <td>tid</td> <td>tid</td> <td>tid</td> <td>tid</td> </tr> <tr> <td>Global Response</td> <td>24</td> <td>24</td> <td>24</td> <td>18</td> </tr> <tr> <td>Percent</td> <td>66.7%</td> <td>77.4%</td> <td>70.6%</td> <td>50.0%</td> </tr> <tr> <td>Sedation (%)</td> <td>7%</td> <td>12%</td> <td>17%</td> <td>5%</td> </tr> <tr> <td>All ADR (%)</td> <td>22%</td> <td>14%</td> <td>29%</td> <td>12%</td> </tr> </tbody> </table>	Groups	Ter	Ter	Chlor	Placebo	N	36	31	34	36	Dose (mg)	200	20	4		Sig:	tid	tid	tid	tid	Global Response	24	24	24	18	Percent	66.7%	77.4%	70.6%	50.0%	Sedation (%)	7%	12%	17%	5%	All ADR (%)	22%	14%	29%	12%
Groups	Ter	Ter	Chlor	Placebo																																								
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Evidence Table 4. Cont.

Ref Num/Author/Source Year	Design/Population	Purpose	Significant Factors	Groups/Outcomes
139 Melillo G., et al. Arzneimittel-Forschung 1982	True Randomization NC Concealed NC Blinding Y Intent to Tx N Seasonal Rhinitis Age: 13-55 years N = 119	To establish the efficacy of terfenadine in combating the symptoms of allergic rhinitis.	Antigen Source: Natural Exposure Pollen Season: Not Considered Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of 7 days Evaluator: Patient Placebo Lead-In: Yes	Groups Ter Chlor Placebo N 41 40 38 Dose (mg) 60 4 Sig: bid 7d tid 7d tid 7d Global Response 29 31 18 Percent 70.0% 77.0% 47.4% Sedation (%) 14.6% 55% 10.0% All ADR (%) Not Reported
235 Brostoff J., et al. Postgraduate Medical Journal. 1982	True Randomization NC Concealed NC Blinding Y Intent to Tx Y Perennial Rhinitis Age: >12 years N = 60	To compare the effects of terfenadine, chlorpheniramine maleate and placebo in patients with perennial or non-seasonal allergic rhinitis.	Antigen Source: Natural Exposure Pollen Season: Not Considered Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of 14 days Evaluator: Patient Placebo Lead-In: No	Groups Ter Chlor Placebo N 20 20 20 Dose (mg) 60 8 Sig: bid 14d bid 14d bid 14d Symptoms Baseline† 7.6 8.0 7.8 Ave Symptoms Score 5.1 4.6 5.8 STD Percent Reduction 12.1% 20.7% 5% Sedation (%) 10% 25% All ADR (%) 38% 53% 20%
236 Backhouse Cf., et al. Practitioner 1982	True Randomization NC Concealed NC Blinding Y Intent to Tx Y Seasonal and Perennial Rhinitis Age: >12 years N = 136	To test these observations in general practice in the UK and to compare clinical efficacy and side effects of terfenadine with those of placebo and of the antihistamine which is most commonly used in the UK, chlorpheniramine maleate.	Antigen Source: Natural Exposure Pollen Season: Not Considered Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of 14 days Evaluator: Patient Placebo Lead-In: No	Groups Ter Chlor Placebo N 44 44 45 Dose (mg) 60 8 Sig: bid 7d bid 7d bid 7d Global Response 32 31 12 Percent 72.7% 69.7% 26.6% Sedation (%) 2.2% 25% 4.4%

Y= Yes, N=No, NC= Not Clear; Ter = Terfenadine, Chlor = Chlorpheniramine; STD = Standard Deviation, SEM = Standard Error of the Mean

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Evidence Table 5. Efficacy and Toxicity of Cetirizine vs Placebo in Children

Ref Num/Author/Source Year	Design/Population	Purpose	Significant Factors	Groups/Outcomes
1 Baelde Y., et al. Drug Investigations. 1992	True Randomization Y Concealed NC Blinding Y Intent to Tx Y Perennial Rhinitis Age: 2-14 years N = 138	To determine an effective and well tolerated dose of cetirizine for the treatment of chronic allergic rhinitis in children aged from 2 to 14 years	Antigen Source: Natural Exposure* Pollen Season: Not Considered Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Average of days 3 and 14 Evaluator: Parents Placebo Lead-In: No	Groups Cet Cet Placebo N 46 46 46 Dose (mg) 5 2.5 Sig: bid 14d bid 14d bid 14d Symptoms Baseline † 13.6 13.6 13.2 Ave Symptoms Score 3.29 4.26 4.97 STD 1 1 1 Percent Reduction 33.8% 14.3% Sedation (%) 0% 6.5% 4.3% All ADR (%) 8.7% 17.4%
87 Jobst S., et al. Allergy. 1994	True Randomization Y Concealed NC Blinding Y Intent to Tx Y Perennial Rhinitis Age: 6-12 years N = 330	To assess the efficacy of three dose levels (2.5, 5, and 10 mg) of cetirizine given once daily in children with perennial allergic rhinitis, in order to investigate the dose response relationship of cetirizine administered once a day and to compare the safety of cetirizine with that of placebo in children aged 6-12 years.	Antigen Source: Natural Exposure Pollen Season: No Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Average of scores at days 7 & 14 Evaluator: Physician Placebo Lead-In: No	Groups Cet Cet Cet Placebo N 76 85 84 83 Dose (mg) 10 5 2.5 Sig: qd 14d qd 14d qd 14d qd 14d Global Response+ 50 56 44 31 Percent 66.2% 66.3% 51.8% 37.6% Symptoms Baseline 2.6 2.75 2.6 2.65 Ave Symptoms Score 1.45 1.6 1.5 1.9 SE 1 1 1 1 Percent Reduction 23.7% 15.8% 21.1% Sedation (%) Not Reported All ADR (%) 22.4% 14.1% 25.0% 18.1%
230 Masi M., et al. Pediatric Allergy and Immunology. 1993	True Randomization Y Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: 6-12 years N = 124	To obtain further evidence to confirm the efficacy and tolerability of a 10 mg daily dose of cetirizine given as 5 mg twice daily in seasonal allergic rhinoconjunctivitis in children.	Antigen Source: Natural Exposure Pollen Season: Yes Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of 14 days Evaluator: Patient Placebo Lead-In: No	Groups Cet Placebo N 63 61 Dose (mg) 5 Sig: bid 14d bid 14d Global Response 49 30 Percent 79% 50% Sedation (%) 9.5% 3.3% All ADR (%) 31.8% 31%

Evidence Table 5. Cont.

Ref Num/Author/Source Year	Design/Population	Purpose	Significant Factors	Groups/Outcomes																																				
231 Allegra L., et al. Pediatric Allergy and Immunology. 1993	True Randomization Y Concealed NC Blinding Y Intent to Tx Y Seasonal Rhinitis Age: 2-6 years N = 107	To examine the therapeutic effects and safety profile of cetirizine in children between 2 and 6 years of age with seasonal rhinitis.	Antigen Source: Natural Exposure Pollen Season: Not Reported Pollen Count: Not Collected Symptom Score: 4 pt Scale Include Nasal Congestion: Yes Data for Evaluation: Ave of days 7 and 14 Evaluator: Physician Placebo Lead-In: No	<table border="0"> <tr> <td>Groups</td> <td>Cet</td> <td>Placebo</td> </tr> <tr> <td>N</td> <td>54</td> <td>53</td> </tr> <tr> <td>Dose (mg)</td> <td>5</td> <td></td> </tr> <tr> <td>Sig:</td> <td>qd 14d</td> <td>qd 14d</td> </tr> <tr> <td>Global Response</td> <td>34</td> <td>24</td> </tr> <tr> <td>Percent</td> <td>63%</td> <td>45.3%</td> </tr> <tr> <td>Symptoms Baseline</td> <td>2.6</td> <td>2.7</td> </tr> <tr> <td>Ave Symptoms Score</td> <td>1.3</td> <td>1.7</td> </tr> <tr> <td>STD</td> <td></td> <td></td> </tr> <tr> <td>Percent Reduction</td> <td>23.5%</td> <td></td> </tr> <tr> <td>Sedation (%)</td> <td>5.6%</td> <td>0%</td> </tr> <tr> <td>All ADR (%)</td> <td>24.1%</td> <td>20.8%</td> </tr> </table>	Groups	Cet	Placebo	N	54	53	Dose (mg)	5		Sig:	qd 14d	qd 14d	Global Response	34	24	Percent	63%	45.3%	Symptoms Baseline	2.6	2.7	Ave Symptoms Score	1.3	1.7	STD			Percent Reduction	23.5%		Sedation (%)	5.6%	0%	All ADR (%)	24.1%	20.8%
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