

Table 8

Summary of Demographic and Baseline Characteristics ---- Protocol NRRJ

Characteristic	Rabeprazole (n= 169)	Ranitidine (n= 169)	Total (n=338)	Between Treatment p-value ^a
Sex				0.559
Male	118 (70%)	113 (67%)	231 (68%)	
Female	51 (30%)	56 (33%)	107 (32%)	
Race				0.140
Caucasian	146 (86%)	156 (92%)	302 (89%)	
African Descent	16 (9%)	7 (4%)	23 (7%)	
Other	7 (4%)	6 (4%)	13 (4%)	
Age (yr)				0.563
Mean	51.4	50.4	50.9	
SD	14.9	14.2	14.5	
Minimum	21	19	19	
Maximum	85	86	86	
Tobacco Consumption				0.128
No	134 (79%)	122 (72%)	256 (76%)	
Yes	35 (21%)	47 (28%)	82 (24%)	
Alcohol Consumption				0.085
No	104 (62%)	119 (70%)	223 (66%)	
Yes	65 (38%)	50 (30%)	115 (34%)	
Caffeine Consumption				0.250
No	40 (24%)	32 (19%)	72 (21%)	
Yes	126 (75%)	137 (81%)	263 (78%)	
Missing	3 (2%)	0 (0%)	3 (1%)	
Antacid Use				0.673
No	59 (35%)	55 (33%)	114 (34%)	
Yes	108 (64%)	111 (66%)	219 (65%)	
Missing	2 (1%)	3 (2%)	5 (1%)	
Number of Doses of Antacid Used per Day (based on average of last three days)				0.972
Mean	2.7	2.7	2.7	
SD	3.6	3.4	3.5	
Minimum	0	0	0	
Maximum	24	20	24	

Copied from Table NRRJ 6.1, page 61, Vol. 164.

^aP-values were obtained by this reviewer using Mantel-Haenszel Chi-Square for endoscopy modified Hetzel-Dent esophagitis grade and gastric ulcer pain frequency grade, using anova for age and number of antacid used per day, and using Chi-Square test for other variables.

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Table 8 (Continued)

Summary of Demographic and Baseline Characteristics ---- Protocol NRRJ

Characteristic	Rabeprazole (n= 169)	Ranitidine (n= 169)	Total (n=338)	Between Treatment p-value
Endoscopy Modified Hetzel-Dent Esophagitis Grade ^b				0.221
0	0 (0%)	0 (0%)	0 (0%)	
1	0 (0%)	0 (0%)	0 (0%)	
2	92 (55%)	81 (48%)	173 (51%)	
3	60 (36%)	69 (41%)	129 (38%)	
4	15 (9%)	19 (11%)	34 (10%)	
5	0 (0%)	0 (0%)	0 (0%)	
Duodenal Ulcer Pain Frequency Grade				0.881
n	167	169	336	
0 = None	5 (3%)	9 (5%)	14 (4%)	
1 = Few	13 (8%)	9 (5%)	22 (7%)	
2 = Several	25 (15%)	24 (14%)	49 (15%)	
3 = Many	32 (19%)	34 (20%)	66 (20%)	
4 = Continual	91 (54%)	91 (54%)	182 (54%)	
Missing	1 (1%)	2 (1%)	3 (1%)	

Copied from Table NRRJ 6.1, page 68, Vol. 164.

*P-values were obtained by this reviewer using Mantel-Haenszel Chi-Square for [redacted] pain frequency grade, using anova for age and number of antacid used per day and using Chi-Square test for other variables.

^b0=Normal mucosa; 1=No macroscopic erosions, but presence of erythema, hyperemia, and/or friability of the esophageal mucosa; 2=Superficial ulceration or erosions involving < 10% of the mucosal surface of the last 5 cm of the esophageal squamous mucosa; 3= Superficial ulceration or erosions involving 10% but <50% of the mucosal surface of the last 5 cm of the esophageal squamous mucosa; 4=Deep ulceration anywhere in the esophagus or confluent erosion of > 50% of the mucosal surface of the last 5 cm of the esophageal squamous mucosa; 5=Stricture.

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Table 9

Summary of Improvement in GERD Heartburn Frequency Grades -Intent to Treat^a
 --- Protocol NRRJ

Frequency Evaluation	Week	Rabeprazole	Ranitidine	P-Value ^b
Improvement ^c	4	121/161 (75%)	91/158 (65%)	< 0.001
	8	127/161 (79%)	108/158 (68%)	0.032
Complete Resolution ^d	4	72/161 (45%)	42/158 (25%)	< 0.001
	8	81/161 (50%)	45/158 (28%)	< 0.001

Copied from Table NRRJ 6.3, page 71, Vol. 164.

^a Patients with normal baseline values (grade=0) were excluded from the analysis.

^b Treatment p-value is adjusted for investigator; obtained using stratified Cochran Mantel-Haenszel statistic.

^c Improvement: Frequency evaluation grade lower than baseline evaluation.

^d Complete resolution: Frequency evaluation grade of 0 (none).

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Table 10

Summary of Improvement in Severity Grades for GERD Heartburn Daytime Pain - Intent to Treat^a.
 ---- Protocol NRRJ

Severity Evaluation	Week	Rabeprazole	Ranitidine	p-value ^b
Improvement ^c	4	95/135 (70%)	84/124 (68%)	0.674
	8	102/135 (76%)	99/124 (80%)	0.409
Complete Resolution ^d	4	79/135 (59%)	53/124 (43%)	0.017
	8	92/135 (68%)	67/124 (59%)	0.025

Copied from Table NRRJ 6.4, page 73, Vol. 164

^a Patients with normal baseline values (grade=0) were excluded from the analysis.

^b Treatment p-value is adjusted for investigator; obtained using stratified Cochran Mantel-Haenszel statistic.

^c Improvement: Severity evaluation grade lower than baseline evaluation.

^d Complete resolution: Severity evaluation grade of 0 (none).

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Table 11

Summary of Improvement in Severity Grades for GERD Heartburn Nighttime Pain - Intent to Treat^a.
 ---- Protocol NRRJ

Severity Evaluation	Week	Rabeprazole	Ranitidine	p-value ^b
Improvement ^c :	4	101/127 (80%)	107/131 (82%)	0.536
	8	110/127 (87%)	113/131 (86%)	0.937
Complete Resolution ^d	4	84/127 (66%)	67/131 (51%)	0.012
	8	94/127 (74%)	74/131 (56%)	0.002

Copied from Table NRRJ 6.5, page 74, Vol. 164.

^a Patients with normal baseline values (grade=0) were excluded from the analysis.

^b Treatment p-value is adjusted for investigator; obtained using stratified Cochran Mantel-Haenszel statistic.

^c Improvement: Severity evaluation grade lower than baseline evaluation.

^d Complete resolution: Severity evaluation grade of 0 (none).

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Table 12

Summary of Improvement in Patients' Overall Well-Being Grades^a ---- Protocol NRRJ

Well-Being Evaluation	Week	Rabeprazole	Ranitidine	p-value ^b
Intent to Treat				
Improvement ^c	4	80/135 (59%)	63/138 (46%)	0.020
	8	86/135 (64%)	73/138 (53%)	0.056
Normalization ^d	4	57/135 (42%)	40/138 (29%)	0.021
	8	62/135 (46%)	42/138 (30%)	0.007

Copied from Table NRRJ 6.6, page 75, Vol. 164

^a Patients with normal baseline values (grade=0) were excluded from the analysis.^b Treatment p-value is adjusted for investigator; obtained using stratified Cochran Mantel-Haenszel statistic.^c Improvement: Well-being evaluation grade lower than baseline evaluation.^d Normalization: Well-being evaluation grade of 0 (very good).APPEARS THIS WAY
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Table 13
 Summary of Antacid Use (Doses Per Day) ---- Protocol NRRJ
 Visit-Wise Analysis

Week	Rabeprazole	Ranitidine	p-Value ^a
<hr/>			
Baseline			
n	165	166	
Mean	2.76	2.73	
SD	3.62	3.38	
Range	0 - 24	0 - 20	
Missing	2	3	
Week 8			
n	60	94	
Mean	0.53	0.65	
SD	0.98	1.02	
Range	0.0 - 3.9	0.0 - 6.6	
Missing	2	6	
Week: 8 Change from Baseline			
n	59	93	
Mean	-1.98	-1.98	0.442
SE	0.32	0.31	
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Copied from Table NRRJ 6.7, page 77, Vol. 164.

^a treatment p-value is adjusted for baseline value and investigator; obtained from ANCOVA (baseline value, investigator, and treatment effect).

Note: At baseline, the mean number of doses of antacid used per day is based on the number of doses taken for the previous 3 days. At Week 4, the mean number of doses of antacid used per day is based on the total number of doses taken since the previous visit divided by the total number of days elapsed.

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Table 14

Summary of Esophagitis Grade at Weeks 4 and 8 by Baseline Esophagitis Grade
 ---- Protocol NRRJ

Treatment	Baseline Grade	n	Esophagitis Grade at Week 4				
			0	1	2	3	4
Rab 20	2	89	55 (62%)	12 (13%)	22 (25%)	0 (0%)	0 (0%)
	3	61	20 (33%)	7 (11%)	28 (46%)	6 (10%)	0 (0%)
	4	15	4 (27%)	0 (0%)	7 (47%)	3 (20%)	1 (7%)
Ran 150	2	76	25 (33%)	9 (12%)	42 (55%)	0 (0%)	0 (0%)
	3	67	17 (25%)	4 (6%)	35 (52%)	11 (16%)	0 (0%)
	4	19	4 (21%)	1 (5%)	7 (37%)	5 (26%)	2 (11%)

Treatment	Baseline Grade	n	Esophagitis Grade at Week 8				
			0	1	2	3	4
Rab 20	2	23	18 (78%)	4 (18%)	1 (4%)	0 (0%)	0 (0%)
	3	31	20 (65%)	3 (10%)	5 (16%)	3 (10%)	0 (0%)
	4	10	3 (30%)	4 (40%)	2 (20%)	0 (0%)	1 (10%)
Ran 150	2	40	13 (33%)	13 (33%)	13 (33%)	0 (0%)	1 (3%)
	3	48	15 (32%)	9 (19%)	13 (27%)	10 (21%)	1 (2%)
	4	14	3 (21%)	3 (21%)	4 (29%)	4 (29%)	0 (0%)

Tables were compiled by the reviewer.

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Table 15

Summary of Demographic and Baseline Characteristics ---- Protocol NRRP

Characteristic	Rabeprazole (n= 100)	Omeprazole (n= 102)	Total (n=202)	Between Treatment p-value ^a
Sex				0.006
Male	53 (53%)	73 (72%)	126 (62%)	
Female	47 (47%)	29 (28%)	76 (38%)	
Race				0.599
Caucasian	97 (97%)	100 (98%)	197 (98%)	
African Descent	1 (1%)	0 (0%)	1 (< 1%)	
Other	2 (2%)	2 (2%)	4 (2%)	
Age (yr)				0.305
Mean	54	52	53	
SD	15.70	15.56	15.63	
Minimum	20	23	20	
Maximum	86	83	86	
Tobacco Consumption				0.925
No	78 (78%)	79 (77%)	157 (78%)	
Yes	22 (22%)	23 (23%)	45 (22%)	
Alcohol Consumption				0.020
No	48 (48%)	33 (32%)	81 (40%)	
Yes	51 (51%)	69 (68%)	120 (59%)	
Missing	1 (1%)	0 (0%)	1 (<1%)	
Caffeine Consumption				0.409
No	9 (9%)	6 (6%)	15 (7%)	
Yes	91 (91%)	95 (94%)	186 (92%)	
Missing	0 (0%)	1 (2%)	1 (<1%)	
Antacid Use				0.686
No	73 (73%)	77 (75%)	150 (74%)	
Yes	27 (27%)	25 (25%)	52 (26%)	
Number of Doses of Antacid Used per Day (based on average of last three days)				0.714
Mean	1.06	0.95	1.00	
SD	2.178	2.046	2.108	
Minimum	0	0	0	
Maximum	10	12	12	

Copied from Table NRRP 6.1, page 67, Vol. 187.

^aP-values were obtained by this reviewer using Mantel-Haenszel Chi-Square for endoscopy modified Hetzel-Dent esophagitis grade, pain frequency grade, using anova for age and number of antacid used per day, and using Chi-Square test for other variables.

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Table 15 (Continued)

Summary of Demographic and Baseline Characteristics ---- Protocol NRRP

Characteristic	Rabeprazole (n= 100)	Omeprazole (n= 102)	Total (n=202)	Between Treatment p-value ^a
Endoscopy Modified Hetzel-Dent Esophagitis Grade ^b				0.521
0	0 (0%)	0 (0%)	0 (0%)	
1	0 (0%)	0 (0%)	0 (0%)	
2	41 (41%)	46 (45%)	87 (43%)	
3	54 (54%)	52 (51%)	106 (52%)	
4	5 (5%)	4 (4%)	9 (4%)	
5	0 (0%)	0 (0%)	0 (0%)	
Duodenal Ulcer Pain Frequency Grade				0.264
0 = None	2(2%)	0 (0%)	2(1%)	
1 = Few	13 (13%)	10 (10%)	23 (11%)	
2 = Several	30 (30%)	22 (22%)	52 (26%)	
3 = Many	22 (22%)	41 (40%)	63 (31%)	
4 = Continual	33 (33%)	29 (28%)	62 (31%)	

Copied from Table NRRP 6.1, page 68, Vol. 187.

^aP-values were obtained by this reviewer using Mantel-Haenszel Chi-Square for endoscopy modified Hetzel-Dent esophagitis grade, pain frequency grade, using anova for age and number of antacid used per day, and using Chi-Square test for other variables.

^b0=Normal mucosa; 1=No macroscopic erosions, but presence of erythema, hyperemia, and/or friability of the esophageal mucosa; 2=Superficial ulceration or erosions involving < 10% of the mucosal surface of the last 5 cm of the esophageal squamous mucosa; 3= Superficial ulceration or erosions involving 10% but <50% of the mucosal surface of the last 5 cm of the esophageal squamous mucosa; 4=Deep ulceration anywhere in the esophagus or confluent erosion of > 50% of the mucosal surface of the last 5 cm of the esophageal squamous mucosa; 5=Stricture.

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Table 16

Summary of Improvement in GERD Heartburn Frequency Grades -Intent to Treat^a
 — Protocol NRRP

Frequency Evaluation	Week	Rabeprazole	Omeprazole	P-value ^b
Improvement ^c	4	67/98 (68%)	76/102 (75%)	0.359
	8	72/98 (73%)	78/102 (76%)	
Complete Resolution ^d	4	29/98 (28%)	27/102 (26%)	0.583
	8	37/98 (38%)	32/102 (31%)	

Copied from Table NRRP 63, page 71, Vol. 187.

^a Patients with normal baseline values (grade=0) were excluded from the analysis.

^b Treatment p-value is adjusted for investigator; obtained using stratified Cochran Mantel-Haenszel statistic.

^c Improvement: Frequency evaluation grade lower than baseline evaluation.

^d Complete resolution: Frequency evaluation grade of 0 (none).

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Table 17

Summary of Improvement in Severity Grades for GERD Heartburn Daytime Pain - Intent to Treat^a.
---- Protocol NRRP

Severity Evaluation	Week	Rabeprazole	Omeprazole	p-value ^b
Improvement ^c	4	78/97 (80%)	74/97 (76%)	0.523
	8	84/97 (87%)	80/97 (82%)	0.446
Complete Resolution ^d	4	60/97 (62%)	59/97 (61%)	0.894
	8	66/97 (68%)	64/97 (66%)	0.751

Copied from Table NRRP 6.4, page 72, Vol. 187

^a Patients with normal baseline values (grade=0) were excluded from the analysis.

^b Treatment p-value is adjusted for investigator; obtained using stratified Cochran Mantel-Haenszel statistic.

^c Improvement: Severity evaluation grade lower than baseline evaluation.

^d Complete resolution: Severity evaluation grade of 0 (none).

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Table 18

Summary of Improvement in Severity Grades for GERD Heartburn Nighttime Pain - Intent to Treat^a.
 ---- Protocol NRRP

Severity Evaluation	Week	Rabeprazole	Omeprazole	p-value ^b
Improvement ^c :	4	55/73 (75%)	55/75 (73%)	0.830
	8	57/73 (78%)	63/75 (84%)	0.435
Complete Resolution ^d	4	45/73 (62%)	43/75 (57%)	0.706
	8	47/73 (64%)	50/75 (67%)	0.709

Copied from Table NRRP 6.5, page 73, Vol. 187.

^a Patients with normal baseline values (grade=0) were excluded from the analysis.

^b Treatment p-value is adjusted for investigator; obtained using stratified Cochran Mantel-Haenszel statistic.

^c Improvement: Severity evaluation grade lower than baseline evaluation.

^d Complete resolution: Severity evaluation grade of 0 (none).

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Table 19

Summary of Improvement in Patients' Overall Well-Being Grades^a ---- Protocol NRRP

Well-Being Evaluation	Week	Rabeprazole	Omeprazole	p-value ^b
Intent to Treat				
Improvement ^c	4	60/94 (64%)	53/93 (57%)	0.306
	8	64/94 (68%)	62/93 (67%)	0.828
Normalization ^d	4	38/94 (40%)	31/93 (33%)	0.331
	8	41/94 (44%)	38/93 (41%)	0.736

Copied from Table NRRP 6.6, page 74, Vol. 187

^a Patients with normal baseline values (grade=0) were excluded from the analysis.^b Treatment p-value is adjusted for investigator; obtained using stratified Cochran Mantel-Haenszel statistic.^c Improvement: Well-being evaluation grade lower than baseline evaluation.^d Normalization: Well-being evaluation grade of 0 (very good).APPEARS THIS WAY
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Table 20
 Summary of Antacid Use (Doses Per Day) ---- Protocol NRRP
 Visit-Wise Analysis

Week	Rabeprazole	Omeprazole	p-Value ^a
Baseline			
n	100	102	
Mean	1.06	0.95	
SD	2.18	2.05	
Range	0 - 10	0 - 12	
Week 8			
n	24	24	
Mean	0.14	0.04	
SD	0.32	0.14	
Range	0 - 1.1	0 - 0.7	
Missing	0	1	
Week: 8 Change from Baseline			
n	24	24	
Mean	-1.90	-0.83	0.194
SE	0.62	0.29	

Copied from Table NRRP 6.7, page 71, Vol. 187.

^a treatment p-value is adjusted for baseline value and investigator; obtained from ANCOVA (baseline value, investigator, and treatment effect).

Note: At baseline, the mean number of doses of antacid used per day is based on the number of doses taken for the previous 3 days. At Week 4, the mean number of doses of antacid used per day is based on the total number of doses taken since the previous visit divided by the total number of days elapsed.

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