

Appendix A – Tables

TABLE 1. TOTAL RASH SCORES (EVALUABLE SUBJECTS) BY STUDY

Table of Total Rash Scores (Evaluable Subjects) by Study					
	Active Treatment		Ointment Base		p-value
	N	Mean	N	Mean	
Average Total Rash Score					
<u>Study USA^a</u>					
Study Day 0	50	5.04	50	5.10	0.913
Study Day 3	50	2.06	49	3.10	0.028*
Study Day 5	49	1.33	47	2.38	0.020*
Study Day 7	49	1.24	46	2.26	0.024*
<u>Study Australia-A^b</u>					
Study Day 0	99	6.52	101	6.73	0.569
Study Day 5	93	2.29	98	4.53	<0.001*
Study Day 7	96	1.61	92	4.03	<0.001*
<u>Study Australia B^b</u>					
Study Day 0	96	7.36	93	6.86	0.808
Study Day 5	93	1.88	87	3.77	<0.001*
Study Day 7	93	1.12	85	3.65	<0.001*
<u>Studies Australia A&B^b</u>					
Study Day 0	195	6.93	194	6.79	0.796
Study Day 3	192	3.59	191	4.49	0.016*
Study Day 5	186	2.09	185	4.17	<0.001*
Study Day 7	189	1.37	177	3.85	<0.001*
^a	Total rash score = sum of individual rash scores at ten body sites; p-values from ANOVA with treatment, investigator and severity at baseline effects.				
^b	Total rash score = sum of individual rash scores at eleven body sites; p-values calculated using a Kruskal-Wallis chi-square test.				
*	p<0.05 for difference between treatment groups.				

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TABLE 2. TOTAL RASH SCORES IN THE PRESENCE OF CANDIDA ALBICANS AT THE INFLAMED RASH SITE AT BASELINE (EVALUABLE SUBJECTS)

Total Rash Scores in the Presence of <i>Candida albicans</i> at the Inflamed Rash Site at Baseline (Evaluable Subjects)					
Average Total Rash Score	Active Treatment		Ointment Base		p-value ^a
<u>Study USA</u>	N	Mean	N	Mean	
<i>C. albicans</i> present					
Study Day 0	16	6.00	18	6.28	0.806
Study Day 3	16	3.00	17	5.71	0.043*
Study Day 5	15	1.87	15	4.60	0.038*
Study Day 7	15	2.20	14	4.50	0.060
<u>Study Australia A</u>	N	Mean	N	Mean	
<i>C. albicans</i> present					
Study Day 0	30	7.77	33	8.42	0.534
Study Day 3	30	4.60	32	7.63	0.002*
Study Day 5	27	2.63	32	8.00	<0.001*
Study Day 7	28	1.36	28	8.22	<0.001*

^a p-values calculated using ANOVA model with treatment effect Study USA or a Kruskal-Wallis chi-square test Study Australia A
^b Total rash score = sum of individual rash scores at each rash site.
* p<0.05 for difference between treatment groups

TABLE 3. GLOBAL CLINICAL IMPRESSION NUMBER OF SUBJECTS WITH MILD OR NO DIAPER DERMATITIS (STUDIES AUSTRALIA A&B)

Global Clinical Impression Number of Subjects with Mild or No Diaper Dermatitis (Studies Australia A&B)			
	Active	Base	p-value ^a
Day 0	99/195 (51%)	95/194 (50%)	0.901
Day 3	156/192 (81%)	128/191 (67%)	0.010*
Day 5	171/186 (92%)	124/185 (67%)	<0.001*
Day 7	178/189 (94%)	125/177 (71%)	<0.001*

^a p-value calculated using a Mantel-Haenszel chi-square test.
* p<0.05 for difference between treatment groups

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TABLE 4. ADVERSE EXPERIENCES IN PHASE III EFFICACY STUDIES

Adverse Experiences in Phase III Efficacy Studies			
Body System Adverse experience	Active (N=23)	Ointment Base (N=54)	Total (N=77)
Body as a Whole			
Fever	2	4	6
Routine vaccination	0	1	1
Reaction to DPT vaccine	1	0	1
Cardiovascular			
4th heart sound audible	0	1	1
Ear, Nose, and Throat			
Cold	3	2	5
Croup	0	1	1
Nasal congestion	1	0	1
Oral thrush	1	5	6
Otitis externa	0	1	1
Otitis media	2	5	7
Rhinitis	1	0	1
Rhinorrhea	1	2	3
Tonsillitis	0	1	1
Tonsillitis / croup	1	0	1
Upper respiratory infection	2	18	20
Eye			
Conjunctivitis	3	1	4
Gastrointestinal			
Diarrhea	2	5	7
Gastric disorder	0	1	1
Gastroenteritis	0	1	1
Vomiting	1	2	3
Musculoskeletal			
Inguinal hernia	0	1	1
Nervous			
Irritability	0	1	1
Hypotonia	1	0	1
Respiratory			
Asthma	0	1	1
Bronchiolitis	0	1	1
Bronchitis	1	2	3
Skin and Appendages			
Abscess right thigh	1	0	1
Erythema multiforme	0	1*	1
Rash	1*	3	4
Seborrheic dermatitis	0	2**	2
Total number of adverse experiences	25	63	88
* Drug-related adverse experience			
**One of these reactions was considered a drug-related adverse experience			

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TABLE 5. CRITERIA USED TO DETERMINE CHOICE OF TREATMENT FOR DIAPER DERMATITIS

<u>Criteria Used</u>	<u>MDs (%) who used criteria</u>	<u>Mean % of times the MD used criteria</u>
- Clinical criteria	99%	95.5%
- Clinical criteria with culture	44%	2.5%
- Clinical criteria with KOH	25%	1.3%
- Clinical criteria, with culture & KOH	15%	0.7%