

## **16.2.7 Adverse Events Listings**

**Listing 16.2.7-1 Adverse Events by Subject**

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R1001		"NONE"					
R1002	Placebo	"Irritability" Irritability General Disorders And Administration Site Conditions	2009-03-22 2009-03-27	UNK/ UNK	No	1/ 4	1/ 1
		"Increased Appetite" Increased Appetite Metabolism And Nutrition Disorders	2009-03-27 2009-03-27	UNK/ UNK	No	1/ 3	1/ 1
R1003	Active	"Sore Gums" Gingival Pain Gastrointestinal Disorders	2009-03-04 2009-03-07	12:00/ 08:00	No	1/ 5	5/ 1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R1004		"NONE"					
R1005	Active	"Diarrhea"	2009-05-17	22:00/	No	1/	2/
		Diarrhoea Gastrointestinal Disorders	2009-05-19	17:00		2	1
		"Colon Polyp"	2009-07-15	15:00/	No	1/	3/
		Colonic Polyp Gastrointestinal Disorders	2009-07-15	UNK		2	1
R1006	Placebo	"Right Ankle Sprain"	2009-06-13	19:00/	No	1/	3/
		Joint Sprain Injury, Poisoning And Procedural Complications	2009-07-28	08:00		1	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

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			Date	Time			
R1007	Active	"Low Back Pain"	2009-04-08	12:00/	No	1/ 1	2/ 1
		Back Pain Musculoskeletal And Connective Tissue Disorders	2009-04-08	21:00			
R1008	Placebo	"Pharyngitis"	2009-03-19	11:30/	No	1/ 3	3/ 1
		Pharyngitis Infections And Infestations	2009-03-28	07:00			
		"Left Shoulder Pain"	2009-04-03	UNK/ ONGOING	No	2/ 1	2/ 3
		Musculoskeletal Pain Musculoskeletal And Connective Tissue Disorders					
"Sore Palate"	2009-04-15	07:00/	No	1/ 4	4/ 1		
Oral Pain Gastrointestinal Disorders	2009-05-10	09:00					

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			Date	Time			
R1008	Placebo	"Pharyngitis" Pharyngitis Infections And Infestations	2009-04-15	07:00/	No	1/	1/
			2009-05-10	09:00		3	1
R1009	Active	"Burning Sensation Of Upper Gums" Gingival Pain Gastrointestinal Disorders	2009-03-16	11:43/	No	1/	1/
			2009-05-10	09:00		5	1
		"Pharyngitis" Pharyngitis Infections And Infestations	2009-03-16	11:43/	No	1/	1/
			2009-05-22	09:08		4	1
"Nausea" Nausea Gastrointestinal Disorders	2009-03-16	11:53/	No	1/	1/		
	2009-04-23	10:00		5	1		

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

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			Date	Time			
R1009	Active	"Otitis Externa" Otitis Externa Infections And Infestations	2009-05-19	07:00/	No	2/	2/
			2009-06-04	10:00		2	1
R1010	Active	"Blood In Stool" Haematochezia Gastrointestinal Disorders	2009-04-17	08:00/	No	1/	1/
			2009-04-19	UNK		1	1
R1011	Placebo	"Headaches" Headache Nervous System Disorders	2009-04-23	20:30/	No	1/	2/
			2009-04-24	04:00		2	1
		"Headache" Headache Nervous System Disorders	2009-05-06	19:00/	No	1/	1/
			2009-05-06	23:00		2	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

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Study Population: ITT

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			Date	Time			
R1012		"NONE"					
R1013	Placebo	"Sore Lips"	2009-04-22	10:05/	No	1/	1/
		Lip Pain	2009-05-06	08:50		5	1
		Gastrointestinal Disorders					
		"Sinusitis"	2009-06-13	08:00/	No	1/	2/
		Sinusitis	2009-06-22	08:00		2	1
		"Cough"	2009-06-13	08:00/	No	1/	1/
		Cough	2009-11-09	UNK		2	1
		Respiratory, Thoracic And Mediastinal Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

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Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R1013	Placebo	"Chest Congestion" Respiratory Tract Congestion Respiratory, Thoracic And Mediastinal Disorders	2009-11-02	06:30/	No	1/	2/
			2009-11-09	UNK		2	1
R1014		"NONE"					
R1015	Active	"Headache" Headache Nervous System Disorders	2009-05-17	16:00/	No	1/	2/
			2009-05-18	20:10		3	1
		"Sinusitis" Sinusitis Infections And Infestations	2009-08-21	UNK/	No	1/	1/
			2009-08-23	08:00		2	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

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			Date	Time			
R1016	Active	"Vomiting"	2009-06-16	08:30/	No	1/ 5	1/ 1
		Vomiting Gastrointestinal Disorders	2009-06-16	08:35			
R1017		"NONE"					
R1018	Placebo	"Metallic Taste"	2009-05-15	11:45/	No	1/ 4	4/ 1
		Dysgeusia Nervous System Disorders	2009-06-18	05:00			
		"Nausea"	2009-05-15	11:45/	No	1/ 4	1/ 1
		Nausea Gastrointestinal Disorders	2009-06-18	05:00			

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			Date	Time			
R1018	Placebo	"Pharyngitis"	2009-06-24	03:30/	No	1/ 3	4/ 1
		Pharyngitis Infections And Infestations	2009-07-18	05:00			
R1019	Active	"Dizziness"	2009-06-01	11:00/	No	1/ 2	1/ 1
		Dizziness Nervous System Disorders	2009-06-01	11:10			
		"Dizziness"	2009-06-15	UNK/	No	1/ 2	1/ 1
		Dizziness Nervous System Disorders	2009-06-15	UNK			
"Low Back Pain(Recurrent)"	2009-09-17	16:00/	No	1/ 2	2/ 1		
Back Pain Musculoskeletal And Connective Tissue Disorders	2009-09-18	06:15					

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			Date	Time						
R1019	Active	"Sinus Headache"	2009-11-29	10:00/	No	1/	2/			
		Sinus Headache	2009-11-29	12:00				2	1	
		Nervous System Disorders								
R1020	Placebo	"Irritability"	2009-07-02	UNK/	No	1/	1/			
		Irritability	2009-07-15	UNK				2	1	
		General Disorders And Administration Site Conditions								
		"Mood Swings"	2009-07-02	UNK/				No	1/	1/
		Mood Swings	2009-07-15	UNK						
		Psychiatric Disorders								
"Back Strain"	2009-08-07	12:00/	No	2/	2/					
Back Injury	2009-08-17	12:00				1	1			
Injury, Poisoning And Procedural Complications										

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			Date	Time			
R1020	Placebo	"Back Pain"	2009-08-31	UNK/	No	2/	3/
		Back Pain	2009-11-02	UNK		2	1
		Musculoskeletal And Connective Tissue Disorders					
R1020	Placebo	"Chest/Nasal Congestion"	2009-09-01	08:00/	No	1/	2/
		Respiratory Tract Congestion	2009-09-06	09:00		2	1
		Respiratory, Thoracic And Mediastinal Disorders					
R1020	Placebo	"Back Pain"	2009-11-02	UNK/	No	1/	3/
		Back Pain	ONGOING			2	2
		Musculoskeletal And Connective Tissue Disorders					
R1021	Placebo	"Headache"	2009-07-23	01:00/	No	1/	2/
		Headache	2009-08-05	UNK		3	1
		Nervous System Disorders					

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R1021	Placebo	"Headcold"	2009-09-14	08:00/	No	1/ 2	2/ 1
		Nasopharyngitis Infections And Infestations	2009-09-28	08:00			
		"Low Back Pain"	2009-11-11	20:00/	No	1/ 2	2/ 1
		Back Pain Musculoskeletal And Connective Tissue Disorders	2009-11-19	08:00			
R1022	Active	"Muscle Strain"	2009-07-04	22:00/	No	1/ 1	1/ 1
		Muscle Strain Injury, Poisoning And Procedural Complications	2009-07-25	08:00			
R1023	Placebo	"Sinusitis"	2009-06-18	14:00/	No	1/ 3	1/ 1
		Sinusitis Infections And Infestations	2009-06-25	08:30			

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			Date	Time			
R1024	Active	"Yeast Vaginitis"	2009-07-08	UNK/	No	1/ 2	2/ 1
		Vulvovaginal Mycotic Infections And Infestations	2009-07-28	08:00			
		"Bronchitis"	2009-09-13	14:00/	No	1/ 2	2/ 1
		Bronchitis Infections And Infestations	2009-10-17	08:00			
R1025	Active	"Light Headedness"	2009-06-26	08:00/	No	1/ 3	1/ 1
		Dizziness Nervous System Disorders	2009-06-26	08:00			
		"Gingivitis"	2009-08-31	08:00/	No	1/ 4	1/ 2
		Gingivitis Gastrointestinal Disorders	ONGOING				

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			Date	Time			
R1026		"NONE"					
R1027	Placebo	"Upper Respiratory Infection" Upper Respiratory Tract Infection Infections And Infestations	2009-07-17 2009-07-26	09:00/ UNK	No	1/ 1	2/ 1
R1028	Placebo	"Light Headed" Dizziness Nervous System Disorders	2009-08-09 2009-08-14	UNK/ 10:00	No	1/ 2	1/ 1
R1029	Active	"Hidradenitis Cyst-Right Buttocks" Hidradenitis Skin And Subcutaneous Tissue Disorders	2009-07-18 2009-07-24	22:00/ UNK	No	1/ 1	2/ 1

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			Date	Time			
R1029	Active	"Vaginal Bleeding With Pregnancy" Vaginal Haemorrhage Reproductive System And Breast Disorders	2009-09-15	UNK/ UNK	Yes	3/ 2	5/
R1030	Placebo	"Cough" Cough Respiratory, Thoracic And Mediastinal Disorders	2009-08-14	06:00/ 08:00	No	1/ 2	1/ 1
			2009-08-30				
		"Nausea" Nausea Gastrointestinal Disorders	2009-08-16 2009-08-19	02:30/ 06:00	No	1/ 2	1/ 1
		"Myalgia" Myalgia Musculoskeletal And Connective Tissue Disorders	2009-08-17 2009-08-19	06:00/ 06:00	No	1/ 2	1/ 1

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			Date	Time					
R1030	Placebo	"Dyspepsia"	2009-08-17	20:00/	No	1/	3/		
		Dyspepsia	2009-08-19	06:00				2	1
		Gastrointestinal Disorders							
R1031	Active	"Fractured Tooth"	2009-12-20	UNK/	No	1/	3/		
		Tooth Fracture	2010-01-07	09:30				1	1
		Injury, Poisoning And Procedural Complications							
R1031	Active	"Hiccup"	2009-07-16	13:00/	No	1/	1/		
		Hiccups	2009-08-06	UNK				3	1
		Respiratory, Thoracic And Mediastinal Disorders							
R1031	Active	"Right Leg Pain"	2009-10-30	UNK/	No	1/	2/		
		Pain In Extremity	ONGOING					1	3
		Musculoskeletal And Connective Tissue Disorders							

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Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R1031	Active	"Vitamin D Deficiency" Vitamin D Deficiency Metabolism And Nutrition Disorders	2009-11-30 ONGOING	UNK/	No	1/ 1	2/ 3
		"Sinusitis" Sinusitis Infections And Infestations	2009-12-26 2010-01-02	12:00/ UNK	No	1/ 2	2/ 1
R1032	Active	"Irritability" Irritability General Disorders And Administration Site Conditions	2009-07-20 2009-08-08	UNK/ UNK	No	1/ 3	1/ 1
		"Increased Appetite" Increased Appetite Metabolism And Nutrition Disorders	2009-07-24 2009-08-08	UNK/ UNK	No	1/ 3	1/ 1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R1032	Active	"Nausea" Nausea Gastrointestinal Disorders	2009-08-02 2009-08-16	13:00/ UNK	No	1/ 4	1/ 1
		"Sinusitis" Sinusitis Infections And Infestations	2009-09-22 2009-09-27	18:00/ UNK		1/ 1	1/ 1
		"Spider Bite" Arthropod Bite Injury, Poisoning And Procedural Complications	2009-10-16 2009-10-25	07:00/ UNK		1/ 1	2/ 1
		"Pharyngitis" Pharyngitis Infections And Infestations	2009-10-25 2009-10-29	07:00/ UNK		1/ 1	1/ 1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R1033	Placebo	"Irritated Gums" Gingival Pain Gastrointestinal Disorders	2009-08-18	18:00/	No	1/	4/
			2009-08-31	11:00		5	1
R1034	Placebo	"Irregular Heart Beat" Heart Rate Irregular Investigations	2009-11-21	UNK/	No	1/	2/
			2009-11-21	UNK		2	1
		"Irregular Heart Beat" Heart Rate Irregular Investigations	2009-12-17	UNK/	No	1/	2/
2009-12-17	UNK	2	1				
		"Musculoskeletal Chest Pain" Musculoskeletal Chest Pain Musculoskeletal And Connective Tissue Disorders	2010-02-09	06:00/	No	1/	1/
			2010-02-09	06:07		2	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>		
			Date	Time					
R1035	Active	"Left Elbow Pain"	2009-09-02	06:00/	No	1/	2/		
		Arthralgia	2009-10-19	UNK				1	1
		Musculoskeletal And Connective Tissue Disorders							
R1035	Active	"Upper Respiratory Infection"	2009-09-20	06:00/	No	1/	2/		
		Upper Respiratory Tract Infection	2009-09-24	05:30				2	1
		Infections And Infestations							
R1035	Active	"Upper Respiratory Infection"	2009-11-09	06:00/	No	1/	2/		
		Upper Respiratory Tract Infection	2009-11-11	06:00				2	1
		Infections And Infestations							
R1036	Placebo	"Numbness Of Gums"	2009-07-31	10:00/	No	1/	1/		
		Hypoaesthesia Oral	2009-08-18	UNK				3	1
		Gastrointestinal Disorders							

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>					
			Date	Time								
R1036	Placebo	"Right Shoulder Pain"	2009-08-11	15:00/	No	1/	2/					
		Musculoskeletal Pain	2009-08-24	16:00				1	1			
		Musculoskeletal And Connective Tissue Disorders										
		"Lacerations To Right Arm"	2009-09-09	07:45/				No	2/	3/		
		Skin Laceration	2009-09-17	UNK							1	1
		Injury, Poisoning And Procedural Complications										
"Lacerations To Right Arm"	2009-09-17	UNK/	No	1/	3/							
Skin Laceration	ONGOING					1	3					
Injury, Poisoning And Procedural Complications												
R1037	Active	"Sneezing"	2009-08-02	10:00/	No	1/	2/					
		Sneezing	2009-08-21	UNK				3	1			
		Respiratory, Thoracic And Mediastinal Disorders										

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>	
			Date	Time				
R1037	Active	"Blister On Roof Of Mouth"	2009-08-09	08:00/	No	1/	2/	
		Blister	2009-08-16	20:00		3	1	
		Skin And Subcutaneous Tissue Disorders						
		"Sore Throat"	2009-08-10	08:00/	No	1/	2/	
Oropharyngeal Pain	2009-08-15	20:00	2	1				
Respiratory, Thoracic And Mediastinal Disorders								
R1037	Active	"Diarrhea"	2009-08-17	20:00/	No	1/	2/	
		Diarrhoea	2009-08-17	22:00		3	1	
Gastrointestinal Disorders								
R1037	Active	"Low Backstrain"	2009-09-07	08:00/	No	2/	2/	
		Back Injury	2009-11-06	UNK		1	1	
Injury, Poisoning And Procedural Complications								

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R1037	Active	"Allergic Reaction(Iodine?)" Hypersensitivity Immune System Disorders	2009-09-29	14:00/	No	1/	2/
			2009-09-29	16:20		2	1
R2001	Active	"Low Back Strain" Back Injury Injury, Poisoning And Procedural Complications	2009-11-06	UNK/	No	1/	2/
			ONGOING			1	2
R2002	Active	"NONE"					
R2002	Active	"Gingival Discomfort" Gingival Pain Gastrointestinal Disorders	2009-04-01	12:00/	No	2/	1/
			2009-04-09	11:00		4	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2002	Active	"Gingival Discomfort"	2009-04-15	10:00/	No	1/ 5	1/ 1
		Gingival Pain	2009-04-30	00:00			
		Gastrointestinal Disorders					
		"Pharyngitis"	2009-04-25	10:00/	No	2/ 3	1/ 1
Pharyngitis	2009-05-10	12:00					
Inflections And Infestations							
"Acne Exacerbation"	Acne	Skin And Subcutaneous Tissue Disorders	2009-04-28	11:00/	No	3/ 2	1/ 1
			2009-05-29	10:30			
"Gingival Bleeding"	Gingival Bleeding	Gastrointestinal Disorders	2009-05-21	03:30/	No	2/ 4	1/ 1
			2009-05-30	10:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2002	Active	"Acne Exacerbation"	2009-05-29	10:30/	No	1/ 2	1/ 1
		Acne Skin And Subcutaneous Tissue Disorders	2009-07-07	13:35			
R2002	Active	"Acne Exacerbation"	2009-07-07	13:35/	No	2/ 2	1/ 2
		Acne Skin And Subcutaneous Tissue Disorders	ONGOING				
R2003	Active	"Sinus Congestion"	2009-06-24	12:00/	No	3/ 2	2/ 1
		Sinus Congestion Respiratory, Thoracic And Mediastinal Disorders	2009-07-02	12:00			
R2003	Active	"Sinus Congestion"	2009-07-02	12:00/	No	1/ 2	2/ 1
		Sinus Congestion Respiratory, Thoracic And Mediastinal Disorders	2009-07-11	UNK			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2004	Placebo	"Headache"	2009-04-04	UNK/	No	1/	2/
		Headache Nervous System Disorders	2009-04-04	UNK		3	1
R2005	Placebo	"Headache"	2009-04-21	07:15/	No	1/	2/
		Headache Nervous System Disorders	2009-04-21	13:00		3	1
		"Xerostomia"	2009-04-28	UNK/	No	1/	1/
		Dry Mouth Gastrointestinal Disorders	2009-05-13	14:00		3	1
"Corneal Ulcer"	2009-06-17	09:00/	No	3/	2/		
Ulcerative Keratitis Eye Disorders	2009-06-23	15:41		1	1		

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2005	Placebo	"Corneal Ulcer" Ulcerative Keratitis Eye Disorders	2009-06-23	15:41/	No	1/	2/
			2009-07-02	14:00		1	1
R2006	Placebo	"Gingival Discomfort" Gingival Pain Gastrointestinal Disorders	2009-03-26	07:52/	No	1/	1/
			2009-03-30	09:00		5	1
		"Chills" Chills General Disorders And Administration Site Conditions	2009-03-26	12:00/	No	1/	1/
			2009-04-10	UNK		2	1
"Nausea" Nausea Gastrointestinal Disorders	2009-03-26	14:00/	No	1/	1/		
	2009-03-26	15:00		3	1		

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2006	Placebo	"Dizziness"	2009-03-29	10:00/	No	1/	1/
		Dizziness	2009-03-29	10:20		2	1
		Nervous System Disorders					
		"Headache"	2009-03-29	13:00/	No	1/	2/
		Headache	2009-03-29	16:00		3	1
		Nervous System Disorders					
		"Bilateral Hand Tremors"	2009-03-30	15:00/	No	1/	1/
		Tremor	2009-04-06	09:00		3	1
Nervous System Disorders							
"Dyspepsia"	2009-03-31	20:00/	No	1/	1/		
Dyspepsia	2009-03-31	21:00		2	1		
Gastrointestinal Disorders							

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2006	Placebo	"Midepigastric Abdominal Pain"	2009-03-31	20:00/	No	2/	1/
		Abdominal Pain	2009-03-31	21:00		2	1
		Gastrointestinal Disorders					
		"Pharyngitis"	2009-04-01	10:00/	No	1/	1/
Pharyngitis	2009-04-01	19:00	2	1			
		Infections And Infestations					
		"Dysphagia"	2009-04-04	07:00/	No	2/	1/
		Dysphagia	2009-04-13	10:00		2	1
		Gastrointestinal Disorders					
		"Throat Discomfort"	2009-04-04	07:00/	No	2/	1/
		Throat Irritation	2009-04-13	10:00		2	1
		Respiratory, Thoracic And Mediastinal Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2006	Placebo	"Nasal Congestion"	2009-04-06	09:00/	No	1/	2/
		Nasal Congestion	2009-04-06	10:00		2	1
		Respiratory, Thoracic And Mediastinal Disorders					
		"Cough"	2009-04-08	12:00/	No	1/	1/
		Cough	2009-04-15	10:00		2	1
		Respiratory, Thoracic And Mediastinal Disorders					
R2007	Placebo	"Headache"	2009-06-24	16:00/	No	1/	2/
		Headache	2009-06-25	09:00		3	1
		Nervous System Disorders					
		"NONE"					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>		
			Date	Time					
R2008	Active	"Gagging"	2009-05-06	10:00/	No	3/	1/		
		Retching	2009-06-11	09:00				5	1
		Gastrointestinal Disorders							
R2008	Active	"Nausea"	2009-05-11	10:00/	No	3/	1/		
		Nausea	2009-06-05	UNK				4	1
		Gastrointestinal Disorders							
R2008	Active	"Vaginitis"	2009-06-01	09:00/	No	3/	2/		
		Vaginal Infection	2009-06-04	UNK				1	1
		Infections And Infestations							
R2008	Active	"Vaginitis"	2009-06-04	UNK/	No	1/	2/		
		Vaginal Infection	2009-06-10	UNK				1	1
		Infections And Infestations							

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2009	Placebo	"Attention Deficit Disorder" Attention Deficit/Hyperactivity Disorder Psychiatric Disorders	2009-09 ONGOING	UNK/	No	2/ 1	2/ 3
R2010	Active	"Flushing Sensation" Flushing Vascular Disorders	2009-04-22 2009-04-22	11:00/ 11:10	No	1/ 4	1/ 1
		"Headache" Headache Nervous System Disorders	2009-04-22 2009-04-22	11:10/ 12:10	No	1/ 3	1/ 1
R2011	Placebo	"Stress" Stress Psychiatric Disorders	2009-05-07 ONGOING	UNK/	No	2/ 1	1/ 2

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2011	Placebo	"Left Eye Injury"	2009-05-17	04:00/	No	3/	2/
		Eye Injury	2009-05-21	06:00		1	1
		Injury, Poisoning And Procedural Complications					
R2011	Placebo	"Left Eye Injury"	2009-05-21	06:00/	No	1/	2/
		Eye Injury	2009-05-22	06:30		1	1
		Injury, Poisoning And Procedural Complications					
R2011	Placebo	"Right Toe Pain"	2009-06-18	21:00/	No	3/	1/
		Pain In Extremity	2009-07-02	06:00		1	1
		Musculoskeletal And Connective Tissue Disorders					
R2011	Placebo	"Right Knee Pain"	2009-09-08	16:30/	No	2/	2/
		Arthralgia	2009-10-02	15:00		1	1
		Musculoskeletal And Connective Tissue Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2012	Active	"Dysgeusia" Dysgeusia Nervous System Disorders	2009-04-27	13:30/	No	2/	1/
			2009-04-30	15:00		4	1
		"Gingival Discomfort" Gingival Pain Gastrointestinal Disorders	2009-04-27	14:00/	No	2/	1/
			2009-05-07	11:00		5	1
	"Intermittent Hiccoughs" Hiccups Respiratory, Thoracic And Mediastinal Disorders	2009-04-28	08:30/	No	1/	1/	
		2009-07-24	10:02		3	1	
		"Throat Irritation" Throat Irritation Respiratory, Thoracic And Mediastinal Disorders	2009-05-01	11:00/	No	2/	1/
			2009-05-05	08:00		3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>	
			Date	Time				
R2012	Active	"Cough"	2009-05-06	13:30/	No	1/	1/	
		Cough	2009-05-09	07:00				2
		Respiratory, Thoracic And Mediastinal Disorders						
		"Dysgeusia"	2009-05-06	13:30/	No	1/	1/	
Dysgeusia	2009-05-09	07:00	4	1				
Nervous System Disorders								
		"Cough"	2009-05-12	15:00/	No	1/	1/	
		Cough	2009-05-14	07:00				2
Respiratory, Thoracic And Mediastinal Disorders								
		"Cough"	2009-05-14	11:30/	No	2/	2/	
		Cough	2009-05-14	11:37				2
Respiratory, Thoracic And Mediastinal Disorders								

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2012	Active	"Intermittent Esophageal Reflux" Gastroesophageal Reflux Disease Gastrointestinal Disorders	2009-05-15 2009-05-21	18:30/ 19:00	No	1/ 3	1/ 1
		"Xerostomia" Dry Mouth Gastrointestinal Disorders	2009-05-20 2009-05-20	07:00/ 15:00		1/ 2	1/ 1
		"Anxiety" Anxiety Psychiatric Disorders	2009-05-28 2009-05-30	19:30/ 15:00		2/ 2	1/ 1
		"Agitation" Agitation Psychiatric Disorders	2009-05-28 2009-05-30	19:30/ 15:00		2/ 2	1/ 1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>	
			Date	Time				
R2012	Active	"Rash"	2009-07-02	15:00/	No	1/	1/	
		Rash	2009-07-03	06:30		2	1	
		Skin And Subcutaneous Tissue Disorders						
		"Rash"	2009-07-03	06:30/	No	2/	1/	
Rash	2009-07-04	17:00	2	1				
Skin And Subcutaneous Tissue Disorders								
R2012	Active	"Rash"	2009-07-04	17:00/	No	3/	1/	
		Rash	2009-07-06	06:32		2	1	
Skin And Subcutaneous Tissue Disorders								
R2012	Active	"Rash"	2009-07-06	06:32/	No	1/	1/	
		Rash	2009-07-10	06:30		2	1	
Skin And Subcutaneous Tissue Disorders								

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2013	Active	"Dyspepsia"	2009-05-07	07:00/	No	2/	1/
		Dyspepsia	2009-05-10	12:00		2	1
		Gastrointestinal Disorders					
		"Nightmare"	2009-05-07	21:00/	No	2/	1/
Nightmare	2009-05-08	07:00	1	1			
		Psychiatric Disorders					
		"Anxiety"	2009-05-14	06:45/	No	2/	1/
		Anxiety	2009-05-14	19:15		1	1
		Psychiatric Disorders					
		"Nightmare"	2009-06-09	22:00/	No	2/	1/
		Nightmare	2009-06-10	06:30		1	1
		Psychiatric Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2013	Active	"Anxiety" Anxiety Psychiatric Disorders	2009-07-05 2009-07-25	21:00/ 21:00	No	2/ 2	1/ 1
		"Dyspepsia" Dyspepsia Gastrointestinal Disorders	2009-07-05 2009-08-12	21:00/ 15:00	No	2/ 2	1/ 1
		"Right Arm Pain" Pain In Extremity Musculoskeletal And Connective Tissue Disorders	2009-08-08 2009-08-10	08:00/ 17:00	No	2/ 1	2/ 1
		"Right Arm Swelling" Oedema Peripheral General Disorders And Administration Site Conditions	2009-08-08 2009-08-10	08:00/ 17:00	No	2/ 1	2/ 1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2013	Active	"Right Shoulder Swelling" Swelling General Disorders And Administration Site Conditions	2009-08-08 2009-09-21	UNK/ UNK	No	2/ 1	2/ 1
		"Right Shoulder Pain" Musculoskeletal Pain Musculoskeletal And Connective Tissue Disorders	2009-08-08 2009-09-21	UNK/ UNK		2/ 1	2/ 1
		"Right Arm Pain" Pain In Extremity Musculoskeletal And Connective Tissue Disorders	2009-08-10 2009-09-10	17:00/ UNK		1/ 1	2/ 1
		"Right Arm Swelling" Oedema Peripheral General Disorders And Administration Site Conditions	2009-08-10 2009-09-10	17:00/ UNK		1/ 1	2/ 1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>					
			Date	Time								
R2014	Placebo	"Dyspepsia"	2009-05-04	17:00/	No	1/	1/					
		Dyspepsia	2009-06-12	18:00				4	1			
		Gastrointestinal Disorders										
		"Nausea"	2009-06-16	UNK/				No	1/	1/		
		Nausea	2009-08-29	UNK							4	1
		Gastrointestinal Disorders										
		"Headache"	2009-07-08	12:00/				No	1/	2/		
		Headache	2009-07-08	15:00							2	1
		Nervous System Disorders										
R2015	Active	"Bronchitis"	2009-05-08	09:00/	No	2/	2/					
		Bronchitis	2009-05-14	07:00				2	1			
		Infections And Infestations										

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2015	Active	"Bronchitis" Bronchitis Infections And Infestations	2009-05-14	07:00/	No	1/	2/
			2009-05-20	05:45		2	1
R2016	Placebo	"Gingival Discomfort" Gingival Pain Gastrointestinal Disorders	2009-05-08	11:10/	No	1/	1/
			2009-06-29	07:30		5	1
R2017	Active	"Fever" Pyrexia General Disorders And Administration Site Conditions	2009-06-20	20:00/	No	2/	2/
			2009-06-27	08:00		1	1
		"Nasal Congestion" Nasal Congestion Respiratory, Thoracic And Mediastinal Disorders	2009-11-15	15:00/	No	1/	2/
			2009-11-28	09:00		1	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2018	Placebo	"Rhinorrhea"	2009-06-27	02:00/	No	2/ 2	1/ 1
		Rhinorrhoea Respiratory, Thoracic And Mediastinal Disorders	2009-06-27	02:05			
R2019	Placebo	"Lumbar Strain"	2009-07-08	19:00/	No	3/ 2	2/ 1
		Back Injury Injury, Poisoning And Procedural Complications	2009-07-13	09:00			
		"Lumbar Strain"	2009-07-13	09:00/	No	2/ 1	2/ 1
Back Injury Injury, Poisoning And Procedural Complications	2009-08-21	UNK					
R2020	Active	"Dyspepsia"	2009-05-27	11:00/	No	1/ 3	1/ 1
		Dyspepsia Gastrointestinal Disorders	2009-06-02	16:30			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2020	Active	"Rhinorrhea" Rhinorrhoea Respiratory, Thoracic And Mediastinal Disorders	2009-05-30 2009-06-02	09:30/ 20:00	No	1/ 3	1/ 1
		"Productive Cough" Productive Cough Respiratory, Thoracic And Mediastinal Disorders	2009-06-02 2009-06-06	08:00/ 09:00		No	2/ 2
		"Gingival Bleeding" Gingival Bleeding Gastrointestinal Disorders	2009-06-20 2009-06-27	09:00/ 09:00	No		1/ 4
		"Gingival Pain" Gingival Pain Gastrointestinal Disorders	2009-06-20 2009-06-27	09:00/ 09:00		No	2/ 4

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>	
			Date	Time				
R2020	Active	"Teeth Discoloration" Tooth Discolouration Gastrointestinal Disorders	2009-06-24	08:00/	No	2/	1/	
			2009-07-07	08:18		4	1	
		"Teeth Discoloration" Tooth Discolouration Gastrointestinal Disorders	2009-07-07	08:18/		No	1/	1/
			2009-07-14	08:00			4	1
R2021	Active	"Lower Gingival Discomfort" Gingival Pain Gastrointestinal Disorders	2009-06-13	06:45/	No	1/	1/	
			2009-07-18	10:00		4	1	
		"Excessive Salivation" Salivary Hypersecretion Gastrointestinal Disorders	2009-06-15	05:30/		No	2/	1/
			2009-06-17	18:00			3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2021	Active	"Dental Discomfort Bilateral Upper Incisors"	2009-07-24	07:30/	No	1/	1/
		Dental Discomfort	2009-08-21	UNK		3	1
		Gastrointestinal Disorders					
R2022	Placebo	"Common Cold"	2009-10-04	UNK/	No	2/	2/
		Nasopharyngitis	2009-10-30	UNK		1	1
		Infections And Infestations					
R2023		"Bacterial Vaginal Infection"	2009-11-06	UNK/	No	1/	2/
		Vaginal Infection	2009-11-30	08:30		1	1
		Infections And Infestations					
R2023		"NONE"					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2024	Active	"Gingival Discomfort" Gingival Pain Gastrointestinal Disorders	2009-07-09	UNK/	No	2/	1/
			2009-07-15	UNK		5	1
		"Gingival Discomfort" Gingival Pain Gastrointestinal Disorders	2009-07-15	UNK/	No	1/	1/
			2009-07-16	UNK		5	1
		"Pharyngitis" Pharyngitis Infections And Infestations	2009-08-15	20:00/	No	1/	1/
			2009-08-23	UNK		2	1
R2025		"NONE"					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2026	Active	"Loose Bowel Movements" Diarrhoea Gastrointestinal Disorders	2009-07-27	20:00/	No	1/	1/
			2009-07-28	06:30		2	1
		"Bronchitis" Bronchitis Infections And Infestations	2009-09-04	13:00/	No	2/	2/
			2009-09-07	19:30		1	1
			2009-09-07	19:30/	No	1/	2/
		2009-10-04	UNK	1		1	
R2027	Active	"Dizziness" Dizziness Nervous System Disorders	2009-07-15	11:00/	No	1/	1/
			2009-07-15	11:03		3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2027	Active	"Upper Respiratory Infection"	2010-01-03	18:00/	No	1/	2/
		Upper Respiratory Tract Infection Infections And Infestations	2010-01-05	20:30		1	1
R2028	Placebo	"Burning Sensation In Upper Gingiva"	2009-07-22	11:04/	No	2/	1/
		Gingival Pain Gastrointestinal Disorders	2009-08-03	UNK		4	1
		"Right Lower Molar Fracture"	2009-12-11	09:00/	No	1/	1/
		Tooth Fracture Injury, Poisoning And Procedural Complications	2010-01-08	UNK		1	1
"Tooth Extraction Pain"	2010-01-08	UNK/	No	2/	2/		
Toothache Gastrointestinal Disorders	2010-01-12	UNK		1	1		

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2029	Placebo	"Gingival Tingling" Paraesthesia Oral Gastrointestinal Disorders	2009-07-23 2009-08-02	12:15/ 08:10	No	2/ 4	1/ 1
		"Gingival Tingling" Paraesthesia Oral Gastrointestinal Disorders	2009-08-02 2009-08-09	08:10/ 09:00	No	1/ 4	1/ 1
		"Forgetfulness" Memory Impairment Nervous System Disorders	2009-08-20 2009-08-31	UNK/ UNK	No	1/ 2	1/ 1
		"Irritability" Irritability General Disorders And Administration Site Conditions	2009-08-20 2009-09-14	UNK/ UNK	No	1/ 3	1/ 1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2029	Placebo	"Fatigue"	2009-09-09	UNK/	No	1/	1/
		Fatigue	2009-09-12	UNK		2	1
		General Disorders And Administration Site Conditions					
R2029	Placebo	"Pharyngitis"	2009-10-28	UNK/	No	1/	1/
		Pharyngitis	2009-12-10	UNK		2	1
		Infections And Infestations					
R2030	Placebo	"Dyspepsia"	2009-08-07	14:00/	No	2/	2/
		Dyspepsia	2009-08-08	12:00		3	1
R2031	Placebo	"Insect Bite"	2009-09-07	10:30/	No	1/	2/
		Arthropod Bite	2009-09-09	15:00		1	1
		Injury, Poisoning And Procedural Complications					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R2032		"NONE"					
R3001	Active	"Nausea"	2009-03-02	UNK/	No	1/	1/
		Nausea	2009-03-23	UNK		5	1
		Gastrointestinal Disorders					
		"Lightheadedness"	2009-03-02	UNK/		1/	1/
		Dizziness	2009-03-23	UNK		5	1
		Nervous System Disorders					
R3002	Placebo	"Increase In Acne Vulgaris Breakouts"	2009-03-02	UNK/	No	1/	1/
		Acne	2009-03-03	UNK		3	1
		Skin And Subcutaneous Tissue Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3002	Placebo	"Insomnia"	2009-03-18	UNK/	No	1/	1/
		Insomnia	2009-04-20	UNK		3	1
		Psychiatric Disorders					
		"Diarrhea"	2009-03-23	UNK/	No	1/	1/
		Diarrhoea	2009-04-04	UNK		2	1
		Gastrointestinal Disorders					
		"Weight Gain"	2009-05-01	UNK/	No	1/	1/
		Weight Increased	ONGOING			3	2
		Investigations					
		"Bilateral Edema Lower Extremities"	2009-05-01	UNK/	No	1/	1/
		Oedema Peripheral	ONGOING			3	2
		General Disorders And Administration Site Conditions					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3003		"NONE"					
R3004		"NONE"					
R3005	Placebo	"Skin Nodule" Skin Nodule Skin And Subcutaneous Tissue Disorders	2009-04-09 2009-05-01	UNK/ UNK	No	1/ 1	1/ 1
R3006	Active	"Gingivitis" Gingivitis Gastrointestinal Disorders	2009-03-03 2009-03-15	10:38/ UNK	No	1/ 5	1/ 1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3006	Active	"Nausea"	2009-03-09	UNK/	No	1/	1/
		Nausea	2009-03-09	UNK		3	1
		Gastrointestinal Disorders					
		"Neck Pain"	2009-03-19	UNK/	No	1/	3/
Neck Pain	ONGOING		2	3			
Musculoskeletal And Connective Tissue Disorders							
R3006	Active	"Gingivitis"	2009-03-29	UNK/	No	1/	1/
		Gingivitis	2009-06-23	UNK		3	1
Gastrointestinal Disorders							
R3006	Active	"Leukoplakia Right Cheek 1x3cm"	2009-04-20	UNK/	No	1/	1/
		Leukoplakia	2009-04-27	UNK		4	1
Skin And Subcutaneous Tissue Disorders							

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3007	Placebo	"Bradycardia"	2009-03-03	UNK/	No	1/	1/
		Bradycardia	2009-03-05	UNK		3	1
		Cardiac Disorders					
R3007	Placebo	"Dental Caries"	2009-05-17	UNK/	No	1/	3/
		Dental Caries	2009-05-17	UNK		2	1
		Gastrointestinal Disorders					
R3008	Placebo	"Erythematous Papular Rash, Right Hip, 2 Inch Diameter"	2009-06-23	UNK/	No	1/	1/
		Rash Papular Skin And Subcutaneous Tissue Disorders	ONGOING			3	2
R3009	Active	"Upper Respiratory Tract Infection"	2009-03-10	UNK/	No	1/	2/
		Upper Respiratory Tract Infection Infections And Infestations	2009-03-22	UNK		1	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3009	Active	"Tooth Hypersensitivity" Sensitivity Of Teeth Gastrointestinal Disorders	2009-03-15	UNK/	No	1/	1/
			2009-04	UNK		3	1
		"Glossitis" Glossitis Gastrointestinal Disorders	2009-04-14	UNK/	No	1/	5/
			2009-05-09	UNK		4	1
"Pharyngitis" Pharyngitis Infections And Infestations	2009-04-20	UNK/	No	1/	5/		
	2009-05	UNK		4	1		
"Allergic Reaction Lip Swelling Lower" Hypersensitivity Immune System Disorders	2009-05-03	UNK/	No	1/	3/		
	2009-05-06	UNK		3	1		

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3010	Placebo	"Increase In Number Of Headaches" Headache Nervous System Disorders	2009-03-15	UNK/	No	1/	2/
			2009-03-16	UNK		2	1
		"Upper Respiratory Tract Infection" Upper Respiratory Tract Infection Infections And Infestations	2009-04-18	UNK/	No	1/	1/
			2009-04-25	UNK		2	1
R3011	Active	"Burning Gums" Gingival Pain Gastrointestinal Disorders	2009-04-06	UNK/	No	1/	1/
			2009-04-09	UNK		3	1
		"Serous Otitis Media" Otitis Media Infections And Infestations	2009-07-15	UNK/	No	1/	1/
			2009-10-05	UNK		1	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3012	Active	"Viral Gastroenteritis" Gastroenteritis Viral Infections And Infestations	2009-04-01	UNK/	No	1/	1/
			2009-04-03	UNK		2	1
		"Dyspepsia" Dyspepsia Gastrointestinal Disorders	2009-04-08	UNK/	No	1/	5/
			2009-04-13	UNK		2	1
"Diarrhea" Diarrhoea Gastrointestinal Disorders	2009-04-08	UNK/	No	1/	5/		
	2009-04-13	UNK		2	1		
"Acne Vulgaris" Acne Skin And Subcutaneous Tissue Disorders	2009-04-10	UNK/	No	1/	5/		
	2009-05-22	UNK		2	1		

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3013	Active	"Pharyngitis" Pharyngitis Infections And Infestations	2009-04-06	UNK/	No	1/	1/
			2009-06-25	UNK		3	1
R3013	Active	"Insomnia" Insomnia Psychiatric Disorders	2009-06-10	UNK/	No	1/	1/
			2009-09-18	UNK		2	1
R3014	Placebo	"Upper Respiratory Tract Infection" Upper Respiratory Tract Infection Infections And Infestations	2009-05-20	UNK/	No	1/	2/
			2009-05-24	UNK		2	1
R3015		"NONE"					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3016	Active	"Singultus" Hiccups Respiratory, Thoracic And Mediastinal Disorders	2009-04-14	UNK/	No	1/	1/
			2009-04-17	UNK		3	1
		"Dyspepsia" Dyspepsia Gastrointestinal Disorders	2009-04-14	UNK/	No	1/	1/
			2009-04-21	UNK		3	1
"Diaphoresis" Hyperhidrosis Skin And Subcutaneous Tissue Disorders	2009-04-14	UNK/	No	1/	1/		
	2009-04-28	UNK		3	1		
		"Hyperhidrosis" Hyperhidrosis Skin And Subcutaneous Tissue Disorders	2009-04-14	UNK/	No	1/	1/
			2009-05-26	UNK		2	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3017	Active	"Pharyngitis"	2009-04-15	UNK/	No	1/	1/
		Pharyngitis	2009-05-12	UNK		3	1
		Infections And Infestations					
R3018	Placebo	"Dyspepsia"	2009-04-15	UNK/	No	1/	1/
		Dyspepsia	2009-05-12	UNK		4	1
		Gastrointestinal Disorders					
R3018	Placebo	"Upper Respiratory Tract Infection"	2009-05-04	UNK/	No	1/	2/
		Upper Respiratory Tract Infection	2009-05-24	UNK		2	1
		Infections And Infestations					
R3018	Placebo	"Dental Pain"	2009-07-03	UNK/	No	1/	2/
		Toothache	2009-08-11	UNK		1	1
		Gastrointestinal Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3019	Placebo	"Insomnia"	2009-05-04	UNK/	No	1/	1/
		Insomnia	2009-06-30	UNK		3	1
		Psychiatric Disorders					
		"Bruxism"	2009-05-07	UNK/	No	1/	1/
Bruxism	2009-06-30	UNK	3	1			
		Psychiatric Disorders					
		"Headaches Intermittent"	2009-05-07	UNK/	No	1/	1/
		Headache	2009-06-30	UNK		3	1
		Nervous System Disorders					
		"Upper Respiratory Tract Infection"	2009-06-16	UNK/	No	1/	2/
		Upper Respiratory Tract Infection	2009-07-04	UNK		2	1
		Infections And Infestations					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3019	Placebo	"Gum Line Discoloration" Gingival Discolouration Gastrointestinal Disorders	2009-07-20	UNK/	No	1/	1/
			2009-11-06	UNK		4	1
R3020	Active	"Gingivitis" Gingivitis Gastrointestinal Disorders	2009-05-04	UNK/	No	1/	1/
			2009-06	UNK		3	1
		"Upper Respiratory Tract Infection" Upper Respiratory Tract Infection Infections And Infestations	2009-05-07	UNK/	No	1/	2/
			2009-05-16	UNK		2	1
"Exacerbation Dyspepsia" Dyspepsia Gastrointestinal Disorders	2009-05-22	UNK/	No	1/	2/		
	2009-07	UNK		3	1		

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3020	Active	"Low Back Pain" Back Pain Musculoskeletal And Connective Tissue Disorders	2009-08-20	17:00/	No	2/	2/
			2009-09-02	UNK		1	1
R3021	Active	"Cough" Cough Respiratory, Thoracic And Mediastinal Disorders	2009-05-26	UNK/	No	1/	1/
			2009	UNK		2	1
R3022	Placebo	"Dental Pain Left Lower Molar" Toothache Gastrointestinal Disorders	2009-08-04	UNK/	No	1/	1/
			2009-11-15	UNK		2	1
		"Dental Pain Lower Left Molar" Toothache Gastrointestinal Disorders	2009-11-15	UNK/ ONGOING	No	2/ 2	1/ 2

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3023	Placebo	"Loose Tooth"	2009-06-03	UNK/	No	1/	1/
		Loose Tooth Gastrointestinal Disorders	ONGOING			2	2
		"Soreness In Gums Behind Front Teeth"	2009-06-10	UNK/	No	1/	3/
		Gingival Pain Gastrointestinal Disorders	2009-06-30	UNK		2	1
R3024		"NONE"					
R3025	Placebo	"Dysesthesia"	2009-06-24	UNK/	No	1/	5/
		Dysaesthesia Nervous System Disorders	2009-06-26	UNK		3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3026		"NONE"					
R3027	Active	"Nausea"	2009-05-13	UNK/	No	1/	1/
		Nausea Gastrointestinal Disorders	2009-05-25	UNK		3	1
		"Vaginosis"	2009-05-30	UNK/	No	1/	2/
		Vaginitis Bacterial Infections And Infestations	2009-06-12	UNK		1	1
"Dental Pain (Left Upper And Lower Molars)"	2009-06-10	UNK/	No	1/	1/		
Toothache Gastrointestinal Disorders	ONGOING			3	2		

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3028	Placebo	"Gingival Pain" Gingival Pain Gastrointestinal Disorders	2009-06-06	UNK/UNK	No	1/3	1/1
		"Acne, Vulgaris" Acne Skin And Subcutaneous Tissue Disorders	2009-06-01 2009-06-12	UNK/UNK	No	1/3	1/1
		"Gingival Pain" Gingival Pain Gastrointestinal Disorders	2009-06-18 2009-06-06	UNK/UNK	No	1/3	1/1
R3029		"NONE"					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3030		"NONE"					
R3031	Active	"Pharyngitis"	2009-05-19	UNK/	No	1/	1/
		Pharyngitis Infections And Infestations	2009-09	UNK		4	1
		"Gingivitis"	2009-05-28	10:00/	No	1/	1/
Gingivitis Gastrointestinal Disorders	2009-06-09	UNK	4	1			
R3031	Active	"Sensitive Teeth"	2009-05-28	UNK/	No	1/	1/
		Sensitivity Of Teeth Gastrointestinal Disorders	2009-06-09	UNK		3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R3031	Active	"Lower Left Molar Pain" Toothache Gastrointestinal Disorders	2009-08-13	UNK/	No	3/	3/
			2009-08-13	UNK		2	1
R3032		"NONE"					
R4001	Placebo	"Agitation" Agitation Psychiatric Disorders	2009-03-02	15:00/	No	1/	1/
			2009-03-02	19:00		3	1
		"Agitation" Agitation Psychiatric Disorders	2009-03-03	06:00/	No	1/	1/
			2009-03-03	09:00		3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4001	Placebo	"Agitation"	2009-03-04	06:00/	No	1/ 3	1/ 1
		Agitation	2009-03-04	09:00			
		Psychiatric Disorders					
R4001	Placebo	"Gingival Pain"	2009-03-05	07:00/	No	1/ 5	1/ 1
		Gingival Pain	2009-03-10	UNK			
		Gastrointestinal Disorders					
R4001	Placebo	"Headache"	2009-03-09	06:00/	No	1/ 2	1/ 1
		Headache	2009-03-09	10:00			
		Nervous System Disorders					
R4002	Active	"Salivation"	2009-03-02	10:20/	No	2/ 4	1/ 1
		Salivary Hypersecretion	2009-03-02	10:30			
		Gastrointestinal Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4002	Active	"Hiccups" Hiccups Respiratory, Thoracic And Mediastinal Disorders	2009-03-02	10:20/	No	2/	1/
			2009-03-02	10:30		4	1
		"Pharyngeal Pain" Oropharyngeal Pain Respiratory, Thoracic And Mediastinal Disorders	2009-03-02	10:20/	No	2/	1/
			2009-03-02	10:45		4	1
	"Hypersalivation" Salivary Hypersecretion Gastrointestinal Disorders	2009-03-03	08:00/	No	1/	1/	
		2009-03-17	10:00		4	1	
		"Dyspepsia" Dyspepsia Gastrointestinal Disorders	2009-03-03	08:00/	No	1/	1/
			2009-03-30	09:00		3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4002	Active	"Anorexia"	2009-03-03	08:00/	No	1/ 3	1/ 1
		Anorexia	2009-04-07	08:30			
		Metabolism And Nutrition Disorders					
R4003	Placebo	"Gingival Pain"	2009-05-01	07:00/	No	2/ 5	1/ 1
		Gingival Pain	2009-05-18	07:00			
		Gastrointestinal Disorders					
R4003	Placebo	"Elevated Blood Pressure"	2009-03-04	15:00/	No	1/ 2	1/ 1
		Blood Pressure Increased	2009-03-10	08:25			
		Investigations					
R4003	Placebo	"Viral Upper Respiratory Infection"	2009-03-24	18:00/	No	1/ 2	1/ 1
		Viral Upper Respiratory Tract Infection	2009-04-03	08:00			
		Infections And Infestations					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4004	Active	"Sinus Infection" Sinusitis Infections And Infestations	2009-03-08	09:00/	No	1/	2/
			2009-03-10	07:00		2	1
		"Gingival Pain" Gingival Pain Gastrointestinal Disorders	2009-03-15	UNK/	No	/	1/
			2009-03-29	UNK		4	1
R4005	Active	"Viral Uri" Viral Upper Respiratory Tract Infection Infections And Infestations	2009-03-15	08:00/	No	1/	2/
			2009-03-19	18:00		2	1
		"Hypersalivation" Salivary Hypersecretion Gastrointestinal Disorders	2009-04-03	08:00/	No	1/	1/
			2009-04-03	18:00		3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4005	Active	"Viral Upper Respiratory Infection"	2009-04-25	18:00/	No	1/ 2	2/ 1
		Viral Upper Respiratory Tract Infection Infections And Infestations	2009-04-30	08:00			
		"Viral Upper Respiratory Infection"	2009-09-13	19:00/	No	1/ 2	1/ 1
		Viral Upper Respiratory Tract Infection Infections And Infestations	2009-09-25	17:00			
R4006	Placebo	"Viral Uri"	2009-03-30	14:00/	No	1/ 2	2/ 1
		Viral Upper Respiratory Tract Infection Infections And Infestations	2009-04-11	22:00			
R4007	Active	"Dysphagia"	2009-03-16	08:00/	No	1/ 3	1/ 1
		Dysphagia Gastrointestinal Disorders	2009-03-19	20:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4007	Active	"Urinary Tract Infection" Urinary Tract Infection Infections And Infestations	2009-03-16	08:00/	No	1/	2/
			2009-03-20	07:00		2	1
		"Discoloration Of Teeth" Tooth Discolouration Gastrointestinal Disorders	2009-03-30	16:00/	No	1/	1/
			2009-04-01	UNK		5	1
		"Gingival Irritation" Gingival Pain Gastrointestinal Disorders	2009-03-30	16:00/	No	1/	1/
			2009-04-05	08:00		3	1
R4008	Active	"Diarrhea" Diarrhoea Gastrointestinal Disorders	2009-03-11	UNK/	No	1/	1/
			2009-03-11	08:05		3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4008	Active	"Nausea" Nausea Gastrointestinal Disorders	2009-03-11 2009-04-30	UNK/ 08:00	No	1/ 5	1/ 1
		"Pharyngeal Pain" Oropharyngeal Pain Respiratory, Thoracic And Mediastinal Disorders	2009-03-11 2009-07-02	UNK/ 06:00		1/ 3	1/ 1
		"Odontalgia" Toothache Gastrointestinal Disorders	2009-03-17 2009-03-19	08:00/ 14:00		1/ 2	1/ 1
		"Rhinorrhea" Rhinorrhoea Respiratory, Thoracic And Mediastinal Disorders	2009-04-01 2009-04-16	08:00/ 08:00		1/ 2	1/ 1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4008	Active	"Left Mandibular Pain"	2009-04-01	UNK/	No	1/ 3	2/ 1
		Pain In Jaw	2009-05-10	05:00			
		Musculoskeletal And Connective Tissue Disorders					
R4008	Active	"Back Pain"	2009-04-03	09:00/	No	1/ 1	2/ 1
		Back Pain	2009-05-04	07:00			
		Musculoskeletal And Connective Tissue Disorders					
R4008	Active	"Contusions From Fall, Face And Right Knee"	2009-04-19	17:00/	No	2/ 1	2/ 1
		Contusion	2009-04-30	05:00			
		Injury, Poisoning And Procedural Complications					
R4009	Placebo	"Arthralgia Left Wrist"	2009-05-14	07:00/	No	1/ 1	2/ 1
		Arthralgia	2009-06-17	06:30			
		Musculoskeletal And Connective Tissue Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4010	Placebo	"Nausea" Nausea Gastrointestinal Disorders	2009-03-27	07:00/	No	1/	1/
			2009-03-27	07:30		3	1
		"Viral Syndrome" Viral Infection Infections And Infestations	2009-04-01	UNK/ UNK	No	/	1/
						1	1
R4010	Placebo	"Arthralgia Left Shoulder" Arthralgia Musculoskeletal And Connective Tissue Disorders	2009-05-19	09:00/	No	1/	2/
			2009-07-29	08:00		1	1
R4010	Placebo	"Odontalgia" Toothache Gastrointestinal Disorders	2009-05-23	08:00/	No	1/	1/
			2009-06-01	08:00		3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4010	Placebo	"Cough"	2009-08-15	08:00/	No	1/	2/
		Cough Respiratory, Thoracic And Mediastinal Disorders	2009-08-20	09:00			
R4011		"NONE"					
R4012	Active	"Hypersalivation"	2009-03-11	10:54/	No	2/	1/
		Salivary Hypersecretion Gastrointestinal Disorders	2009-04-25	22:00			
		"Epistaxis"	2009-04-09	05:00/	No	1/	1/
		Epistaxis Respiratory, Thoracic And Mediastinal Disorders	2009-04-10	22:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4012	Active	"Epistaxis"	2009-04-25	13:00/	No	1/	1/
		Epistaxis Respiratory, Thoracic And Mediastinal Disorders	2009-04-25	13:20		2	1
R4013		"NONE"					
R4014	Placebo	"Viral Upper Respiratory Infection"	2009-04-04	09:45/	No	1/	2/
		Viral Upper Respiratory Tract Infection Infections And Infestations	2009-04-15	09:00		2	1
		"Back Strain"	2009-07-02	06:15/	No	2/	2/
		Back Injury Injury, Poisoning And Procedural Complications	ONGOING			1	3

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4015	Placebo	"Gingival Pain" Gingival Pain Gastrointestinal Disorders	2009-03-11	12:58/	No	1/	3/
			2009-07-29	08:34		5	1
		"Gingival Papules" Oropharyngeal Blistering Respiratory, Thoracic And Mediastinal Disorders	2009-03-12	08:00/	No	1/	1/
			2009-03-20	06:30		4	1
	"Mood Disturbance" Mood Altered Psychiatric Disorders	2009-03-12	08:00/	No	1/	1/	
		2009-08-07	07:00		2	1	
	"Nausea" Nausea Gastrointestinal Disorders	2009-03-12	09:00/	No	1/	1/	
		2009-07-29	08:34		5	1	

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4015	Placebo	"Insomnia"	2009-03-13	22:00/	No	1/	1/
		Insomnia	2009-07-29	UNK		2	1
		Psychiatric Disorders					
		"Hearing Loss"	2009-03-18	19:00/	No	1/	1/
Deafness	2009-03-28	06:00	2	1			
		Ear And Labyrinth Disorders					
		"Bruxism"	2009-03-18	UNK/	No	1/	1/
		Bruxism	UNK	UNK		1	1
		Psychiatric Disorders					
		"Constipation"	2009-03-30	08:00/	No	2/	1/
		Constipation	2009-04-01	08:00		2	1
		Gastrointestinal Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4015	Placebo	"Constipation"	2009-04-02	08:00/	No	1/	1/
		Constipation	2009-04-04	08:00		3	1
		Gastrointestinal Disorders					
		"Oral Mucosa Chemical Burn"	2009-04-15	13:00/	No	2/	1/
Caustic Injury	2009-07-01	11:30	4	1			
Injury, Poisoning And Procedural Complications							
"Flatulence"	Flatulence	Gastrointestinal Disorders	2009-04-18	08:00/	No	1/	1/
			2009-05-06	00:00		3	1
"Constipation"	Constipation	Gastrointestinal Disorders	2009-04-18	08:00/	No	1/	2/
			2009-05-20	10:00		3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4015	Placebo	"Pruritus Ear"	2009-04-21	07:30/	No	1/ 2	1/ 1
		Ear Pruritus	2009-04-22	23:00			
		Ear And Labyrinth Disorders					
R4016	Active	"Dry Mouth"	2009-05-20	07:00/	No	1/ 3	1/ 1
		Dry Mouth	2009-07-29	07:00			
		Gastrointestinal Disorders					
R4016	Active	"Dyspepsia"	2009-03-13	15:00/	No	1/ 4	1/ 1
		Dyspepsia	2009-03-15	20:00			
		Gastrointestinal Disorders					
R4016	Active	"Nasal Congestion"	2009-03-20	12:00/	No	1/ 2	2/ 1
		Nasal Congestion	2009-03-23	08:00			
		Respiratory, Thoracic And Mediastinal Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4016	Active	"Back Pain"	2009-04-14	18:15/	No	2/ 1	2/ 1
		Back Pain Musculoskeletal And Connective Tissue Disorders	2009-04-24	08:00			
		"Left Ankle Sprain"	2009-05-21	17:30/	No	2/ 1	2/ 1
		Joint Sprain Injury, Poisoning And Procedural Complications	2009-08-25	17:00			
R4017	Active	"Rhinorrhea"	2009-03-25	11:00/	No	1/ 2	2/ 1
		Rhinorrhoea Respiratory, Thoracic And Mediastinal Disorders	2009-03-26	14:00			
		"Polyphagia"	2009-03-28	14:00/	No	1/ 3	1/ 1
		Hyperphagia Metabolism And Nutrition Disorders	UNK	UNK			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4017	Active	"Viral Upper Respiratory Infection"	2009-04-16	14:00/	No	1/ 2	1/ 1
		Viral Upper Respiratory Tract Infection Infections And Infestations	2009-04-28	08:00			
R4018	Placebo	"Viral Uri"	2009-03-19	13:00/	No	1/ 2	2/ 1
		Viral Upper Respiratory Tract Infection Infections And Infestations	2009-03-29	08:00			
		"Nasal Congestion"	2009-04-07	08:00/			
		Nasal Congestion Respiratory, Thoracic And Mediastinal Disorders	2009-04-12	UNK			
		"Strep Pharyngitis"	2009-05-05	08:00/	No	2/ 2	2/ 1
		Pharyngitis Streptococcal Infections And Infestations	2009-05-09	07:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>		
			Date	Time					
R4018	Placebo	"Otitis Media"	2009-05-06	09:00/	No	1/	2/		
		Otitis Media	2009-09-09	07:00				2	1
		Infections And Infestations							
R4018	Placebo	"Fever"	2009-07-29	09:00/	No	1/	2/		
		Pyrexia	2009-07-31	12:00				1	1
		General Disorders And Administration Site Conditions							
R4018	Placebo	"Abdominal Pain"	2009-07-29	09:00/	No	1/	2/		
		Abdominal Pain	2009-08-18	08:00				2	1
		Gastrointestinal Disorders							
R4019	Placebo	"Dysmenorrhea"	2009-05-13	08:00/	No	1/	2/		
		Dysmenorrhoea	2009-05-14	08:00				1	1
		Reproductive System And Breast Disorders							

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4019	Placebo	"Mild Upper Respiratory Infection" Upper Respiratory Tract Infection Infections And Infestations	2009-10-07	19:00/	No	1/	2/
			2009-10-11	09:00		2	1
R4020	Active	"Headache" Headache Nervous System Disorders	2009-04-01	UNK/ UNK	No	/	2/
						2	1
			2009-04-06	UNK/ UNK		/	2/
					No	2	1
		"Sinus Headache" Sinus Headache Nervous System Disorders	2009-04-15	UNK/ UNK	No	/	2/
						2	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4020	Active	"Viral Uri" Viral Upper Respiratory Tract Infection Infections And Infestations	2009-04-20	08:00/	No	1/	2/
			2009-05-10	08:00		2	1
R4021	Placebo	"Gingival Pain" Gingival Pain Gastrointestinal Disorders	2009-03-30	16:10/	No	1/	1/
			2009-04-18	08:00		4	1
R4022		"NONE"					
R4023	Placebo	"Gingival Pain" Gingival Pain Gastrointestinal Disorders	2009-04-06	08:00/	No	1/	1/
			2009-04-10	08:00		4	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4024	Active	"Pharyngeal Pain"	2009-04-20	12:00/	No	1/ 3	1/ 1
		Oropharyngeal Pain Respiratory, Thoracic And Mediastinal Disorders	2009-05-20	07:00			
R4024	Active	"Back Pain"	2009-05-08	14:00/	No	1/ 1	2/ 3
		Back Pain Musculoskeletal And Connective Tissue Disorders	ONGOING				
R4025	Active	"Gingival Edema"	2009-04-03	15:00/	No	1/ 4	1/ 1
		Gingival Oedema Gastrointestinal Disorders	2009-04-04	15:00			
R4025	Active	"Gingival Pain"	2009-04-08	16:00/	No	1/ 4	1/ 1
		Gingival Pain Gastrointestinal Disorders	2009-04-08	22:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4025	Active	"Dry Mouth"	2009-04-23	08:00/	No	1/ 5	1/ 1
		Dry Mouth Gastrointestinal Disorders	2009-05-06	10:00			
R4025	Active	"Dysgeusia"	2009-04-23	08:00/	No	1/ 5	1/ 1
		Dysgeusia Nervous System Disorders	2009-05-06	10:00			
R4026	Placebo	"Cough"	2009-07-25	22:00/	No	1/ 2	2/ 1
		Cough Respiratory, Thoracic And Mediastinal Disorders	2009-07-28	08:00			
R4027	Active	"Hypersalivation"	2009-04-22	08:00/	No	1/ 3	1/ 1
		Salivary Hypersecretion Gastrointestinal Disorders	2009-04-25	08:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4027	Active	"Gingival Pain"	2009-04-22	UNK/	No	1/	1/
		Gingival Pain	2009-06-30	12:00		5	1
		Gastrointestinal Disorders					
		"Insect Bites"	2009-07-11	09:00/	No	1/	2/
Arthropod Bite	2009-07-15	08:00	1	1			
		Injury, Poisoning And Procedural Complications					
		"Insect Bite"	2009-08-03	14:00/	No	1/	2/
		Arthropod Bite	2009-08-07	11:50		1	1
		Injury, Poisoning And Procedural Complications					
		"Headache"	2009-08-04	15:00/	No	1/	2/
		Headache	2009-08-05	11:50		1	1
		Nervous System Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4028	Active	"Urinary Tract Infection" Urinary Tract Infection Infections And Infestations	2009-07-30	05:00/	No	1/	2/
			2009-08-01	05:00		2	1
R4029	Placebo	"Gingival Pain" Gingival Pain Gastrointestinal Disorders	2009-04-23	UNK/	No	1/	1/
			2009-05-03	08:00		4	1
R4030		"Headache" Headache Nervous System Disorders	2009-04-26	11:30/	No	1/	2/
			2009-04-26	12:30		2	1
R4030		"NONE"					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4031	Placebo	"Dyspepsia" Dyspepsia Gastrointestinal Disorders	2009-04-28	14:00/	No	1/	1/
			2009-05-02	08:00		3	1
R4032	Placebo	"Viral Upper Respiratory Infection" Viral Upper Respiratory Tract Infection Infections And Infestations	2009-10-27	10:00/	No	/	2/
			2009-11-07	08:00		1	1
R4033	Active	"Gingival Pain" Gingival Pain Gastrointestinal Disorders	2009-04-27	UNK/	No	1/	1/
			2009-05-18	08:00		4	1
		"Hiccups" Hiccups Respiratory, Thoracic And Mediastinal Disorders	2009-04-27	UNK/	No	1/	1/
			2009-06-15	08:00		4	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4033	Active	"Serous Otitis"	2009-06-01	08:00/	No	1/	2/
		Otitis Media	2009-06-06	08:00		2	1
		Inflections And Infestations					
		"Constipation"	2009-06-04	16:00/	No	1/	2/
Constipation	2009-06-05	20:00	2	1			
		Gastrointestinal Disorders					
		"Contact Dermatitis"	2009-06-06	08:00/	No	1/	2/
		Dermatitis Contact	2009-06-12	20:00		1	1
		Skin And Subcutaneous Tissue Disorders					
		"Laceration Left Leg"	2009-06-14	13:00/	No	2/	2/
		Skin Laceration	2009-06-23	09:00		1	1
		Injury, Poisoning And Procedural Complications					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4033	Active	"Insomnia"	2009-06-14	22:00/	No	1/	2/
		Insomnia	2009-06-14	23:30		1	1
		Psychiatric Disorders					
		"Vaginal Candidiasis"	2009-06-15	08:00/	No	1/	2/
Vulvovaginal Candidiasis	2009-06-16	08:00	1	1			
		Infections And Infestations					
R4033	Active	"Laceration Left Leg"	2009-06-23	09:00/	No	1/	3/
		Skin Laceration	2009-07-21	08:00		1	1
		Injury, Poisoning And Procedural Complications					
R4033	Active	"Dizziness"	2009-07-01	08:00/	No	1/	1/
		Dizziness	2009-07-07	08:00		2	1
		Nervous System Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4033	Active	"Right Rotator Cuff Tear"	2009-08-28	11:00/	No	/ 1	/ 
		Rotator Cuff Syndrome Musculoskeletal And Connective Tissue Disorders	ONGOING				
R4033	Active	"Sinusitis"	2009-09-02	08:00/	No	1/ 2	2/ 1
		Sinusitis Infections And Infestations	2009-09-11	08:00			
R4034		"NONE"					
R4035	Active	"Pharyngeal Pain"	2009-05-13	15:00/	No	1/ 2	2/ 1
		Oropharyngeal Pain Respiratory, Thoracic And Mediastinal Disorders	2009-05-15	12:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4035	Active	"Headache"	2009-05-14	19:00/	No	2/ 2	2/ 1
		Headache	2009-05-15	00:00			
		Nervous System Disorders					
		"Headache"	2009-05-29	22:30/	No	1/ 2	1/ 1
Headache	2009-05-30	01:00					
Nervous System Disorders							
"Headache"	2009-05-31	22:00/	No	1/ 2	2/ 1		
Headache	2009-06-01	00:00					
Nervous System Disorders							
"Gingival Pain"	2009-06-15	UNK/	No	/ 4	1/ 1		
Gingival Pain	UNK	UNK					
Gastrointestinal Disorders							

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4035	Active	"Nausea"	2009-06-22	09:00/	No	1/	1/
		Nausea Gastrointestinal Disorders	2009-06-23	12:00			
		"Viral Upper Respiratory Infection"	2009-07-30	10:00/	No	1/	2/
		Viral Upper Respiratory Tract Infection Infections And Infestations	2009-08-05	08:00			
R4036	Placebo	"Pharyngeal Pain"	2009-05-05	13:13/	No	1/	1/
		Oropharyngeal Pain Respiratory, Thoracic And Mediastinal Disorders	2009-05-05	22:00			
R4037	Placebo	"Laceration Left Hand"	2009-06-06	UNK/	No	1/	2/
		Skin Laceration Injury, Poisoning And Procedural Complications	2009-06-26	11:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4037	Placebo	"Viral Syndrome" Viral Infection Infections And Infestations	2009-07-11	00:00/	No	1/	1/
			2009-07-16	08:00		1	1
R4038	Placebo	"Sinusitis" Sinusitis Infections And Infestations	2009-05-26	07:00/	No	2/	2/
			2009-06-16	UNK		2	1
			2009-06-16	UNK/		1/	2/
		"Sinusitis" Sinusitis Infections And Infestations	2009-06-30	08:00	No	2	1
R4039	Active	"Cough" Cough Respiratory, Thoracic And Mediastinal Disorders	2009-11-03	20:00/	No	1/	2/
			2009-11-10	20:00		2	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4040	Active	"Nausea"	2009-06-08	UNK/	No	/ 3	1/ 1
		Nausea	2009-06-08	UNK			
		Gastrointestinal Disorders					
R4040	Active	"Gastroenteritis"	2009-09-15	08:00/	No	1/ 1	2/ 1
		Gastroenteritis	2009-09-22	09:54			
		Infections And Infestations					
R4040	Active	"Myalgia - Hips And Shoulder"	2009-11-09	10:00/	No	1/ 1	2/ 3
		Myalgia	ONGOING				
		Musculoskeletal And Connective Tissue Disorders					
R4041	Placebo	"Headache"	2009-05-15	06:00/	No	1/ 2	2/ 1
		Headache	2009-05-15	13:00			
		Nervous System Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4041	Placebo	"Low Back Pain"	2009-08-11	08:00/	No	1/ 1	1/ 1
		Back Pain Musculoskeletal And Connective Tissue Disorders	2009-08-14	13:00			
R4042	Active	"Otitis Media"	2009-06-27	08:00/	No	1/ 2	2/ 1
		Otitis Media Infections And Infestations	2009-07-07	08:00			
R4043	Active	"Dyspepsia"	2009-05-12	09:00/	No	1/ 3	1/ 1
		Dyspepsia Gastrointestinal Disorders	2009-05-12	12:00			
		"Dysphagia"	2009-05-19	08:00/	No	1/ 3	1/ 1
		Dysphagia Gastrointestinal Disorders	2009-05-19	10:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4044		"NONE"					
R4045	Placebo	"Insomnia"	2009-06-10	23:30/	No	1/	2/
		Insomnia Psychiatric Disorders	2009-09-10	21:00		3	1
		"Gingival Pain"	2009-06-12	07:10/	No	1/	1/
		Gingival Pain Gastrointestinal Disorders	2009-07-21	UNK		3	1
		"Headache"	2009-07-28	10:00/	No	1/	2/
		Headache Nervous System Disorders	2009-07-28	13:00		2	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4045	Placebo	"Headache"	2009-08-04	14:00/	No	/ 1	2/ 1
		Headache Nervous System Disorders	2009-08-04	17:00			
R4046	Placebo	"Viral Syndrome"	2009-05-18	17:00/	No	1/ 2	2/ 1
		Viral Infection Infections And Infestations	2009-05-20	21:00			
R4047	Placebo	"Myalgia Legs"	2009-06-05	22:00/	No	1/ 2	1/ 1
		Myalgia Musculoskeletal And Connective Tissue Disorders	2009-06-13	22:00			
R4048	Active	"Insomnia"	2009-05-20	23:30/	No	1/ 3	1/ 1
		Insomnia Psychiatric Disorders	2009-08-07	07:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4048	Active	"Headache"	2009-05-22	15:00/	No	1/	1/
		Headache	2009-07-02	09:00		3	1
		Nervous System Disorders					
		"Anxiety"	2009-06-01	10:00/	No	1/	1/
		Anxiety	2009-08-27	07:00		1	1
		Psychiatric Disorders					
		"Nightmare"	2009-06-04	02:30/	No	2/	1/
		Nightmare	2009-06-05	23:30		2	1
		Psychiatric Disorders					
		"Fatigue"	2009-06-16	08:00/	No	1/	1/
		Fatigue	2009-08-27	07:00		2	1
		General Disorders And Administration Site Conditions					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4049	Active	"Viral Upper Respiratory Infection"	2009-11-20	08:00/	No	1/	2/
		Viral Upper Respiratory Tract Infection Infections And Infestations	2009-11-27	18:00		2	1
R4050		"NONE"					
R4051		"NONE"					
R4052		"NONE"					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4053	Active	"Sinusitis" Sinusitis Infections And Infestations	2009-08-11	08:00/	No	1/	2/
			2009-08-21	08:00		2	1
R4054	Placebo	"Mucosal Pain Mouth" Pain General Disorders And Administration Site Conditions	2009-06-11	UNK/ UNK	No	/	1/
						3	
R4055	Active	"Nicotine Withdrawal" Drug Withdrawal Syndrome General Disorders And Administration Site Conditions	2009-07-20	12:00/	No	1/	1/
			2009-08-06	05:30		3	1
		"Mood Disturbance" Mood Altered Psychiatric Disorders	2009-07-20	12:00/	No	1/	1/
			2009-09-25	09:00		3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>		
			Date	Time					
R4055	Active	"Nicotine Craving"	2009-09-17	05:45/	No	1/	1/		
		Nicotine Dependence	2009-09-24	10:00				2	1
		Psychiatric Disorders							
R4055	Active	"Otitis"	2009-09-24	12:00/	No	1/	2/		
		Ear Infection	2009-11-11	08:00				1	1
		Infections And Infestations							
R4055	Active	"Cough"	UNK	UNK/	No	/	2/		
		Cough	UNK	UNK				2	
		Respiratory, Thoracic And Mediastinal Disorders							
R4056	Active	"Oral Pain"	2009-06-15	15:00/	No	/	1/		
		Oral Pain	2009-06-17	03:00				3	1
		Gastrointestinal Disorders							

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4056	Active	"Mood Disturbance"	2009-06-15	UNK/	No	/	1/
		Mood Altered	2009-06-17	UNK		2	1
		Psychiatric Disorders					
		"Nausea"	2009-06-22	15:00/	No	/	1/
Nausea	2009-06-23	03:00	2	1			
		Gastrointestinal Disorders					
		"Dyspepsia"	2009-07-06	16:00/	No	/	1/
		Dyspepsia	2009-07-06	18:00		2	1
		Gastrointestinal Disorders					
		"Mood Disturbance"	2009-07-20	15:00/	No	/	1/
		Mood Altered	2009-07-20	17:00		2	1
		Psychiatric Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4056	Active	"Mood Disturbance"	2009-07-22	07:00/	No	1/	1/
		Mood Altered	2009-07-22	15:00			
		Psychiatric Disorders					
		"Anxiety"	2009-08	/	No	/	1/
Anxiety	2009-08	UNK					
Psychiatric Disorders							
		"Mood Disturbance"	2009-08	/	No	/	1/
		Mood Altered	2009-08	UNK			
		Psychiatric Disorders					
		"Dyspepsia"	2009-08-04	12:00/	No	1/	1/
		Dyspepsia	2009-08-04	15:00			
		Gastrointestinal Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4057	Active	"Headache"	2009-06-12	10:00/	No	1/ 3	1/ 1
		Headache	2009-06-18	10:00			
		Nervous System Disorders					
R4057	Active	"Right Ankle Sprain"	2009-07-15	17:00/	No	2/ 1	1/ 1
		Joint Sprain	2009-08-15	08:00			
		Injury, Poisoning And Procedural Complications					
R4058	Placebo	"Nausea"	2009-08-20	UNK/	No	/ 3	1/ 1
		Nausea	2009-10-01	06:00			
R4059	Placebo	"Upper Respiratory Infection"	2009-09-28	05:30/	No	1/ 2	1/ 1
		Upper Respiratory Tract Infection	2009-10-08	08:00			
R4059	Placebo	Infections And Infestations					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4060	Placebo	"Pharyngeal Pain"	2009-06-19	07:00/	No	1/	1/
		Oropharyngeal Pain	2009-06-22	07:00		3	1
		Respiratory, Thoracic And Mediastinal Disorders					
		"Odontalgia"	2009-07-12	00:00/	No	1/	2/
		Toothache	2009-07-14	20:00		2	1
		Gastrointestinal Disorders					
		"Dyspepsia"	2009-07-30	22:00/	No	2/	2/
		Dyspepsia	2009-07-31	01:00		2	1
		Gastrointestinal Disorders					
		"Viral Upper Respiratory Infection"	2009-09-04	08:00/	No	1/	2/
		Viral Upper Respiratory Tract Infection	2009-10-01	06:00		2	1
		Infections And Infestations					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4061	Active	"Nausea" Nausea Gastrointestinal Disorders	2009-06-18 2009-07-14	10:00/ 20:00	No	1/ 3	1/ 1
		"Nasal Congestion" Nasal Congestion Respiratory, Thoracic And Mediastinal Disorders	2009-06-19 2009-07-22	07:00/ 20:00		1/ 3	1/ 1
		"Headache" Headache Nervous System Disorders	2009-06-19 2009-07-22	07:00/ 20:00		1/ 3	2/ 1
		"Emesis" Vomiting Gastrointestinal Disorders	2009-06-19 2009-07-22	08:00/ 00:00		1/ 5	1/ 1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4061	Active	"Dyspepsia"	2009-07-14	20:00/	No	1/ 3	1/ 1
		Dyspepsia Gastrointestinal Disorders	2009-07-22	20:00			
R4062	Placebo	"Anxiety"	2009-06-21	09:00/	No	1/ 2	1/ 1
		Anxiety Psychiatric Disorders	2009-11-10	09:00			
		"Muscle Spasm"	2009-06-30	08:00/	No	1/ 2	1/ 1
Muscle Spasms Musculoskeletal And Connective Tissue Disorders	2009-09-03	08:00					
		"Neuralgia Right Leg"	2009-06-30	08:00/	No	1/ 1	2/ 1
		Neuralgia Nervous System Disorders	2009-11-20	22:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4062	Placebo	"Hearing Loss"	2009-07-13	08:00/	No	1/ 2	1/ 1
		Deafness	2009-08-13	08:00			
		Ear And Labyrinth Disorders					
R4062	Placebo	"Back Pain"	2009-07-13	08:00/	No	1/ 2	1/ 1
		Back Pain	2009-10-01	08:00			
		Musculoskeletal And Connective Tissue Disorders					
R4062	Placebo	"Mood Disturbance"	2009-07-23	05:30/	No	1/ 2	1/ 1
		Mood Altered	2009-07-23	18:00			
		Psychiatric Disorders					
R4062	Placebo	"Headache"	2009-08-20	08:00/	No	1/ 2	1/ 1
		Headache	2009-08-20	12:00			
		Nervous System Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4062	Placebo	"Dyspepsia"	2009-09-03	08:00/	No	1/ 3	2/ 1
		Dyspepsia Gastrointestinal Disorders	2009-10-11	10:00			
		"Arthralgia Bilateral Feet"	2009-09-10	06:00/	No	1/ 1	1/ 1
		Arthralgia Musculoskeletal And Connective Tissue Disorders	2009-09-13	12:00			
R4063	Active	"Lightheaded"	2009-06-20	14:00/	No	1/ 4	1/ 1
		Dizziness Nervous System Disorders	2009-06-28	10:00			
		"Dizziness"	2009-06-25	16:00/	No	1/ 3	1/ 1
		Dizziness Nervous System Disorders	2009-06-26	14:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4063	Active	"Gingival Pain"	2009-06-25	16:00/	No	1/	1/
		Gingival Pain Gastrointestinal Disorders	2009-06-26	14:00		3	1
R4064	Placebo	"Cough"	2009-08-24	09:00/	No	1/	2/
		Cough Respiratory, Thoracic And Mediastinal Disorders	2009-09-08	12:00		2	1
R4065	Active	"Gingival Pain"	2009-06-18	16:00/	No	1/	1/
		Gingival Pain Gastrointestinal Disorders	2009-07-02	12:00		5	1
		"Headache"	2009-07-29	11:00/	No	1/	2/
		Headache Nervous System Disorders	2009-07-29	12:00		2	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4065	Active	"Cough"	2009-09-08	19:00/	No	1/ 2	2/ 1
		Cough Respiratory, Thoracic And Mediastinal Disorders	2009-10-25	12:00			
		"Dysgeusia"	2009-12-30	09:15/	No	2/ 3	1/ 1
		Dysgeusia Nervous System Disorders	2009-12-30	13:30			
R4066	Placebo	"Dental Pain"	2009-08-15	06:30/	No	1/ 5	3/ 1
		Toothache Gastrointestinal Disorders	2009-08-22	06:30			
R4067	Placebo	"Gingival Pain"	2009-06-18	17:00/	No	1/ 4	1/ 1
		Gingival Pain Gastrointestinal Disorders	2009-08-02	07:30			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4067	Placebo	"Nausea"	2009-06-18	UNK/	No	1/	1/
		Nausea Gastrointestinal Disorders	2009-06-20	14:00		4	1
		"Arthralgia Knee"	2009-06-29	08:00/	No	2/	2/
		Arthralgia Musculoskeletal And Connective Tissue Disorders	ONGOING			1	3
R4068	Active	"Hiccups"	2009-06-19	UNK/	No	1/	1/
		Hiccups Respiratory, Thoracic And Mediastinal Disorders	2009-09-01	06:00		5	1
		"Pedal Edema"	2009-08-18	21:00/	No	1/	3/
		Oedema Peripheral General Disorders And Administration Site Conditions	2009-08-28	06:00		2	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4068	Active	"Viral Syndrome" Viral Infection Infections And Infestations	2009-09-24	06:00/	No	2/	2/
			2009-09-29	06:00		2	1
R4069	Active	"Nausea" Nausea Gastrointestinal Disorders	2009-06-23	UNK/	No	1/	1/
			2009-08-10	08:00		4	1
			2009-09-02	08:30/		No	1/
2009-09-02	08:45	2	1				
		"Dyspepsia" Dyspepsia Nervous System Disorders	2009-09-02	14:30/	No	1/	1/
			2009-09-02	15:00		2	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4070	Placebo	"Gingival Pain"	2009-06-26	17:00/	No	1/	1/
		Gingival Pain	2009-06-28	22:00		4	1
		Gastrointestinal Disorders					
		"Back Pain"	2009-08-06	22:00/	No	2/	2/
		Back Pain	2009-08-08	12:00		1	1
		Musculoskeletal And Connective Tissue Disorders					
		"Dental Infection"	2009-09-01	08:00/	No	1/	2/
		Tooth Infection	2009-09-08	08:00		2	1
		Infections And Infestations					
		"Dental Infection"	2009-09-08	08:00/	No	2/	2/
		Tooth Infection	2009-09-19	08:00		2	1
		Infections And Infestations					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4070	Placebo	"Viral Upper Respiratory Infection"	2010-02-15	07:00/	No	1/ 1	1/ 1
		Viral Upper Respiratory Tract Infections And Infestations	2010-02-26	10:00			
R4071	Active	"Headache"	2009-06-26	12:35/	No	1/ 2	1/ 1
		Headache Nervous System Disorders	2009-10-18	12:00			
		"Fatigue"	2009-06-26	16:00/	No	1/ 3	1/ 1
Fatigue General Disorders And Administration Site Conditions	2009-07-07	14:00					
		"Insomnia"	2009-06-26	20:00/	No	1/ 3	1/ 1
		Insomnia Psychiatric Disorders	2009-07-07	07:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>		
			Date	Time					
R4072	Placebo	"Excessive Thirst"	2009-06-26	13:01/	No	1/	1/		
		Thirst	2009-10-23	05:30				4	1
		General Disorders And Administration Site Conditions							
R4072	Placebo	"Palpitations"	2009-07-17	14:00/	No	1/	1/		
		Palpitations	2009-07-17	14:20				2	1
		Cardiac Disorders							
R4072	Placebo	"Hypertriglyceridemia"	2009-07-27	16:30/	No	1/	2/		
		Hypertriglyceridaemia	ONGOING					1	3
		Metabolism And Nutrition Disorders							
R4073	Active	"Hiccups"	2009-06-29	12:30/	No	1/	1/		
		Hiccups	2009-07-17	18:00				3	1
		Respiratory, Thoracic And Mediastinal Disorders							

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4073	Active	"Headache"	2009-06-30	12:00/	No	1/ 3	1/ 1
		Headache	2009-07-02	06:00			
		Nervous System Disorders					
		"Constipation"	2009-07-01	09:00/			
		Constipation	2009-07-09	09:00			
		Gastrointestinal Disorders					
R4074		"Skin Infection Back Of Neck"	2009-08-12	08:00/	No	1/ 1	3/ 1
		Skin Infection	2009-08-25	10:00			
		Infections And Infestations					
		"NONE"					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4075	Active	"Gingival Pain"	2009-07-07	08:00/	No	1/	1/
		Gingival Pain	2009-07-08	07:30		4	1
		Gastrointestinal Disorders					
		"Gingival Pain"	2009-07-21	08:00/	No	1/	1/
Gingival Pain	2009-07-25	UNK	3	1			
		Gastrointestinal Disorders					
		"Pain Left Face"	2009-08-10	08:00/	No	1/	1/
		Facial Pain	2009-08-15	08:00		2	1
		General Disorders And Administration Site Conditions					
		"Nasal Congestion"	2009-08-22	08:00/	No	1/	2/
		Nasal Congestion	2009-09-03	12:00		2	1
		Respiratory, Thoracic And Mediastinal Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>		
			Date	Time					
R4075	Active	"Bronchitis"	2009-09-12	08:00/	No	1/	2/		
		Bronchitis	2009-09-22	08:00				2	1
		Infections And Infestations							
R4076	Placebo	"Nasal Congestion"	2009-10-28	06:30/	No	1/	2/		
		Nasal Congestion	2009-11-02	08:00				2	1
		Respiratory, Thoracic And Mediastinal Disorders							
R4076	Placebo	"Glossitis"	2009-07-06	10:00/	No	1/	1/		
		Glossitis	2009-07-08	09:45				3	1
		Gastrointestinal Disorders							
R4076	Placebo	"Sinusitis"	2009-07-13	07:30/	No	1/	1/		
		Sinusitis	2009-07-20	UNK				2	1
		Infections And Infestations							

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4077		"NONE"					
R4078		"NONE"					
R4079	Placebo	"Gastritis"	2009-10-19	01:00/	No	1/	1/
		Gastritis Gastrointestinal Disorders	2009-10-20	00:00		1	1
R4079	Placebo	"Pneumonia"	2009-11-03	12:00/	No	/	2/
		Pneumonia Infections And Infestations	2009-11-12	12:00		1	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4080		"NONE"					
R4081	Active	"Dyspepsia" Dyspepsia Gastrointestinal Disorders	2009-06-29 2009-07-20	16:00/ 09:00	No	1/ 3	1/ 1
		"Gingival Pain" Gingival Pain Gastrointestinal Disorders	2009-07-06 2009-07-20	13:00/ 09:00	No	1/ 4	1/ 1
R4082	Placebo	"Insomnia" Insomnia Psychiatric Disorders	2009-07-07 2009-08-28	20:00/ 20:00	No	1/ 3	2/ 1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4082	Placebo	"MRSA" Staphylococcal Infection Infections And Infestations	2009-07-25	19:00/	No	2/	2/
			2009-08-22	15:00		1	1
			2009-08-12	UNK/ UNK		No	/
R4083		"NONE"					
R4084	Placebo	"Gingival Pain" Gingival Pain Gastrointestinal Disorders	2009-07-01	15:35/	No	1/	1/
			2009-07-09	18:00		4	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4084	Placebo	"Concussion" Concussion Injury, Poisoning And Procedural Complications	2009-09-19 UNK	10:00/ UNK	No	2/ 1	3/
		"Scalp Laceration" Skin Laceration Injury, Poisoning And Procedural Complications	2009-09-19 UNK	10:00/ UNK			
R4085	Active	"Allergic Reaction-Hands" Hypersensitivity Immune System Disorders	2009-07-03	20:00/	No	1/ 1	2/ 1
			2009-07-06	08:30			
R4086		"NONE"					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4087	Placebo	"Bronchitis"	2009-08-17	08:00/	No	1/ 2	2/ 1
		Bronchitis	2009-08-22	08:00			
		Infections And Infestations					
		"Depression"	2009-09-13	06:30/			
		Depression	ONGOING				
		Psychiatric Disorders					
R4088	Placebo	"Insomnia"	2009-09-19	04:00/	No	1/ 2	1/ 2
		Insomnia	ONGOING				
		Psychiatric Disorders					
		"Back Pain"	2009-08-10	16:46/			
		Back Pain	2009-08-20	08:00			
		Musculoskeletal And Connective Tissue Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4089	Placebo	"Contact Dermatitis Right Leg And Arm" Dermatitis Contact Skin And Subcutaneous Tissue Disorders	2009-07-09	11:00/	No	1/	2/
			2009-07-20	07:00		1	1
		"Contact Dermatitis" Dermatitis Contact Skin And Subcutaneous Tissue Disorders	2009-09-01	11:00/	No	1/	2/
			2009-09-14	08:00		1	1
R4090	Active	"Gingival Pain" Gingival Pain Gastrointestinal Disorders	2009-07-09	07:30/	No	1/	1/
			2009-08-04	07:30		4	1
		"Dizziness" Dizziness Nervous System Disorders	2009-10-22	08:30/	No	1/	1/
			2009-10-22	19:00		4	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4091	Active	"Hordeolum"	2009-07-03	06:30/	No	1/	3/
		Hordeolum	2009-07-08	18:00		1	1
		Infections And Infestations					
		"Headache"	2009-07-06	08:00/	No	1/	2/
Headache	2009-07-06	21:00	1	1			
		Nervous System Disorders					
		"Gingival Pain"	2009-07-09	16:30/	No	1/	1/
		Gingival Pain	2009-07-11	14:00		3	1
		Gastrointestinal Disorders					
		"Viral Upper Respiratory Infection"	2009-08-12	17:00/	No	1/	1/
		Viral Upper Respiratory Tract Infection	2009-08-18	14:00		2	1
		Infections And Infestations					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4091	Active	"Headache"	2010-02-03	10:00/	No	1/	2/
		Headache Nervous System Disorders	2010-02-03	13:00		2	1
R4092	Active	"Sinusitis"	2009-07-08	11:00/	No	1/	2/
		Sinusitis Infections And Infestations	2009-07-26	08:00		2	1
R4093		"NONE"					
R4094		"NONE"					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4095		"NONE"					
R4096	Placebo	"Ankle Sprain"	2009-07-21	11:30/	No	1/	2/
		Joint Sprain	2009-07-23	09:00		1	1
		Injury, Poisoning And Procedural Complications					
		"Influenza"	2009-07-26	09:00/	No	1/	2/
Influenza	2009-08-03	08:00	1	1			
		Infections And Infestations					
		"Neuralgia Upper Extremity"	2009-08-19	11:26/	No	1/	2/
		Neuralgia	2009-08-19	15:00		1	1
		Nervous System Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4096	Placebo	"Neuralgia Upper Extremity" Neuralgia Nervous System Disorders	2009-08-19	15:00/	No	2/	2/
			2009-09-02	09:00		1	1
R4097	Active	"Eczema Chest" Eczema Skin And Subcutaneous Tissue Disorders	2009-07-27	12:00/	No	1/	2/
			2009-10-24	11:00		1	1
			2009-08-14	20:30/		No	1/
2009-08-15	08:00	2	1				
R4098	Placebo	"Headache" Headache Nervous System Disorders	2009-07-21	UNK/	No	/	2/
			2009-07-21	UNK		2	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4098	Placebo	"Viral Upper Respiratory Infection"	2009-09-24	17:00/	No	1/ 2	2/ 1
		Viral Upper Respiratory Tract Infection Infections And Infestations	2009-09-26	08:00			
R4099	Active	"Sinusitis"	2009-07-18	07:00/	No	1/ 2	2/ 1
		Sinusitis Infections And Infestations	2009-07-22	07:00			
		"Back Pain"	2009-07-26	02:00/	No	1/ 1	2/ 1
Back Pain Musculoskeletal And Connective Tissue Disorders	2009-08-30	07:00					
		"Sinusitis"	2009-11-13	09:00/	No	1/ 2	2/ 1
		Sinusitis Infections And Infestations	2009-11-18	09:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4100	Active	"Gingival Pain"	2009-07-09	14:30/	No	1/	1/
		Gingival Pain	2009-07-11	08:00		4	1
		Gastrointestinal Disorders					
		"Gingival Pain"	2009-07-15	09:00/	No	1/	1/
Gingival Pain	2009-07-16	07:00	3	1			
		Gastrointestinal Disorders					
		"Back Pain"	2009-08-19	10:00/	No	1/	2/
		Back Pain	2009-08-19	13:00		1	1
		Musculoskeletal And Connective Tissue Disorders					
		"Anxiety"	2009-11-20	09:00/	No	1/	2/
		Anxiety	ONGOING			2	3
		Psychiatric Disorders					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4101	Placebo	"Headache"	2009-07-19	13:00/	No	1/ 2	2/ 1
		Headache Nervous System Disorders	2009-07-19	15:00			
R4102	Placebo	"Gingival Pain"	2009-07-29	20:00/	No	1/ 4	1/ 1
		Gingival Pain Gastrointestinal Disorders	2009-07-29	20:15			
R4103		"NONE"					
R4104		"NONE"					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4105	Active	"Tooth Pain" Toothache Gastrointestinal Disorders	2010-01-28	11:00/	No	1/	2/
			2010-02-11	06:30		1	1
R4106		"NONE"					
R4107	Active	"Dyspepsia" Dyspepsia Gastrointestinal Disorders	2009-07-24	08:00/	No	1/	1/
			2009-08-23	08:00		4	1
		"Facial Lacerations" Skin Laceration Injury, Poisoning And Procedural Complications	2009-08-14	20:20/	No	1/	3/
			2009-08-19	06:00		1	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4107	Active	"Left Side Facial Contusion" Contusion Injury, Poisoning And Procedural Complications	2009-08-14 2009-08-23	20:20/ 13:30	No	1/ 1	1/ 1
		"Arthralgia Right Wrist" Arthralgia Musculoskeletal And Connective Tissue Disorders	2009-08-14 2009-09-09	20:20/ 08:00	No	2/ 1	2/ 1
		"Abrasion Left Knee" Excoriation Injury, Poisoning And Procedural Complications	2009-08-14 2009-09-09	20:20/ 08:00	No	1/ 1	2/ 1
		"Left Finger Laceration" Skin Laceration Injury, Poisoning And Procedural Complications	2009-08-14 2009-09-09	20:20/ 08:00	No	1/ 1	2/ 1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>		
			Date	Time					
R4107	Active	"Burn Left Hand"	2009-08-14	20:20/	No	1/	2/		
		Thermal Burn	2009-09-09	08:00				1	1
		Injury, Poisoning And Procedural Complications							
R4107	Active	"Arthralgia Right Wrist"	2009-09-09	08:00/	No	1/	2/		
		Arthralgia	2009-11-12	12:00				1	1
		Musculoskeletal And Connective Tissue Disorders							
R4107	Active	"Viral Gastritis"	2009-09-16	20:00/	No	1/	3/		
		Gastritis Viral	2009-09-19	15:00				2	1
		Infections And Infestations							
R4108	Placebo	"Dyspepsia"	2009-07-27	12:00/	No	1/	1/		
		Dyspepsia	2009-08-14	12:00				4	1
		Gastrointestinal Disorders							

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4108	Placebo	"Viral Upper Respiratory Infection"	2009-08-31	08:00/	No	1/	2/
		Viral Upper Respiratory Tract Infection	2009-09-08	20:00		2	1
		Infections And Infestations					
		"Hypertension"	2009-09-04	17:00/	No	1/	2/
Hypertension	2009-09-22	09:00	2	1			
		Vascular Disorders					
		"Viral Upper Respiratory Infection"	2009-09-08	20:00/	No	2/	2/
		Viral Upper Respiratory Tract Infection	2009-09-21	08:00		2	1
		Infections And Infestations					
		"Viral Upper Respiratory Infection"	2009-09-21	08:00/	No	1/	2/
		Viral Upper Respiratory Tract Infection	2009-09-28	08:00		2	1
		Infections And Infestations					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4109	Placebo	"Skin Infection Left Hand" Skin Infection Infections And Infestations	2009-07-24	13:00/	No	1/	2/
			2009-08-11	20:00		2	1
R4110	Active	"Pharyngeal Pain" Oropharyngeal Pain Respiratory, Thoracic And Mediastinal Disorders	2009-07-23	14:00/	No	1/	1/
			2009-08-09	14:30		3	1
		"Abdominal Pain" Abdominal Pain Gastrointestinal Disorders	2009-08-13	09:30/	No	2/	3/
2009-09-07	14:00		1	1			
R4111		"NONE"					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4112	Active	"Viral Upper Respiratory Infection" Viral Upper Respiratory Tract Infection Infections And Infestations	2009-08-31	22:00/	No	1/	1/
			2009-09-05	06:00		2	1
R4113	Active	"Dyspepsia" Dyspepsia Gastrointestinal Disorders	2009-07-30	10:00/	No	1/	1/
			2009-07-30	11:00		3	1
		"Contact Dermatitis" Dermatitis Contact Skin And Subcutaneous Tissue Disorders	2009-08-29	07:00/	No	1/	2/
2009-09-07	10:00	1	1				
		"Cervical Myalgia" Myalgia Musculoskeletal And Connective Tissue Disorders	2010-01-30	11:00/	No	2/	2/
			ONGOING			1	3

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4114	Placebo	"Vaginitis" Vaginal Infection Infections And Infestations	2009-08-19 2009-09-07	08:00/ 10:00	No	1/ 1	2/ 1
		"Viral Respiratory Infection" Respiratory Tract Infection Viral Infections And Infestations	2009-12-26 2010-01-10	05:00/ 13:00	No	1/ 1	2/ 1
		"Visual Disturbance Secondary To Cerebrovascular Accident" Visual Impairment Eye Disorders	2010-01-26 ONGOING	UNK/ UNK	Yes	3/ 1	1/ 2
		"Cerebrovascular Accident" Cerebrovascular Accident Nervous System Disorders	UNK ONGOING	UNK/ UNK	Yes	3/ 1	1/ 2

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4115	Active	"Numbness Right Upper Extremity" Hypoaesthesia Nervous System Disorders	2009-08-17	12:00/	No	1/	1/
			2009-08-18	12:00		1	1
R4116	Placebo	"Viral Upper Respiratory Infection" Viral Upper Respiratory Tract Infection Infections And Infestations	2009-09-22	14:30/	No	1/	2/
			2009-09-23	16:00		2	1
R4117	Active	"Dyspepsia" Dyspepsia Gastrointestinal Disorders	2009-07-25	18:00/	No	1/	2/
			2009-12-18	UNK		3	1
		"Night Sweats" Night Sweats Skin And Subcutaneous Tissue Disorders	2009-08-07	03:00/	No	2/	1/
			2009-12-18	08:00		3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4117	Active	"Corneal Abrasion" Corneal Abrasion Injury, Poisoning And Procedural Complications	2009-08-07	08:00/	No	1/	2/
			2009-08-11	16:00		1	1
		"Anxiety" Anxiety Psychiatric Disorders	2009-10-01	15:00/	No	2/	1/
			2010-02-04	UNK		1	1
"Insomnia" Insomnia Psychiatric Disorders	2009-10-22	02:30/	No	1/	1/		
	ONGOING			1	2		
		"Night Sweats" Night Sweats Skin And Subcutaneous Tissue Disorders	2009-12-18	08:00/	No	1/	1/
			2010-01-20	06:30		3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4117	Active	"Sinus Infection"	2010-01-08	06:00/	No	2/ 1	2/ 1
		Sinusitis Infections And Infestations	2010-01-18	14:00			
R4118	Placebo	"Gingival Pain"	2009-07-24	05:00/	No	1/ 3	1/ 1
		Gingival Pain Gastrointestinal Disorders	2009-07-31	05:00			
		"Papules - Gums"	2009-07-27	05:00/	No	1/ 3	1/ 1
		Oropharyngeal Blistering Respiratory, Thoracic And Mediastinal Disorders	2009-07-31	05:00			
"Stomatitis"	2009-07-28	05:00/	No	1/ 3	1/ 1		
Stomatitis Gastrointestinal Disorders	2009-07-31	05:00					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R4118	Placebo	"Gingivitis" Gingivitis Gastrointestinal Disorders	2009-07-29	08:00/	No	1/	2/
			2009-08-01	07:00		3	1
R4119		"NONE"					
R4120	Active	"Hiccups" Hiccups Respiratory, Thoracic And Mediastinal Disorders	2009-08-13	05:15/	No	1/	1/
			2009-11-20	09:00		4	1
R4121	Placebo	"Headache" Headache Nervous System Disorders	2009-08-02	09:00/	No	1/	2/
			2009-08-02	10:00		2	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>		
			Date	Time					
R4121	Placebo	"Headache"	2009-08-18	14:00/	No	1/	2/		
		Headache	2009-08-20	20:00				2	1
		Nervous System Disorders							
R5001	Placebo	"Sneezing"	2009-06-30	12:00/	No	1/	1/		
		Sneezing	2009-07-03	19:00				4	1
		Respiratory, Thoracic And Mediastinal Disorders							
		"Dyspepsia"	2009-07-07	15:00/				No	1/
Dyspepsia	2009-09-30	06:30	4	1					
		Gastrointestinal Disorders							
		"Lightheadedness Secondary To Venipuncture"	2010-01-11	14:23/	No	1/	3/		
		Dizziness	2010-01-11	14:52				1	1
		Nervous System Disorders							

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R5002		"NONE"					
R5003	Placebo	"Upper Respiratory Infection" Upper Respiratory Tract Infection Infections And Infestations	2009-10-11 2009-11-09	UNK/ 09:00	No	1/ 1	2/ 1
R5004	Active	"Headache" Headache Nervous System Disorders	2009-07-07 2009-07-07	19:00/ 20:00	No	1/ 3	1/ 1
		"Abdominal Pain" Abdominal Pain Gastrointestinal Disorders	2009-07-10 2009-07-10	05:15/ 11:15	No	1/ 2	1/ 1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R5004	Active	"Abdominal Pain" Abdominal Pain Gastrointestinal Disorders	2009-07-22	05:00/	No	1/	1/
			2009-07-22	22:00		2	1
		"Headache" Headache Nervous System Disorders	2009-07-22	05:00/	No	1/	1/
			2009-07-22	22:00		2	1
R5005	Placebo	"Tooth Sensitivity" Sensitivity Of Teeth Gastrointestinal Disorders	UNK	UNK/	No	1/	1/
			UNK	UNK		3	2
R5006	Active	"Exacerbation Of Pre-Existing Neck Pain" Neck Pain Musculoskeletal And Connective Tissue Disorders	2009-07-15	07:00/	No	1/	2/
			2009-10-01	08:00		1	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R5006	Active	"Insomnia"	2009-07-20	02:00/	No	1/	1/
		Insomnia Psychiatric Disorders	UNK	UNK			
R5007	Placebo	"Allergic Rhinitis"	2009-11-02	12:00/	No	1/	2/
		Rhinitis Allergic Respiratory, Thoracic And Mediastinal Disorders	2010-02-16	UNK			
R5007		"NONE"					
R5008	Placebo	"Burning Sensation In Gums"	2009-07-07	14:00/	No	1/	1/
		Gingival Pain Gastrointestinal Disorders	2009-09-30	10:00			

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R5008	Placebo	"Nausea"	2009-07-07	UNK/	No	1/	1/
		Nausea	2009-07-07	UNK		3	1
		Gastrointestinal Disorders					
R5008	Placebo	"Hypothyroidism"	2009-07-28	08:00/	No	1/	2/
		Hypothyroidism	ONGOING			1	3
		Endocrine Disorders					
R5008	Placebo	"Urinary Tract Infection"	2009-10-12	08:00/	No	2/	2/
		Urinary Tract Infection	2009-10-25	20:00		1	1
		Infections And Infestations					
R5009		"NONE"					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R5010	Active	"Tingling To Gums"	2009-07	UNK/	No	1/	1/
		Paraesthesia Oral	2009-08	UNK			
		Gastrointestinal Disorders					
		"Anxiousness"	2009-08	UNK/	No	1/	1/
	Anxiety	2009-08	UNK				
	Psychiatric Disorders						
		"Nausea"	2009-08	UNK/	No	1/	1/
	Nausea	2009-08	UNK				
	Gastrointestinal Disorders						
		"Headache"	2009-08	UNK/	No	1/	1/
	Headache	2009-08	UNK				
	Nervous System Disorders						

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R5011	Active	"Diarrhea" Diarrhoea Gastrointestinal Disorders	2009-08-13	14:30/	No	1/	1/
			2009-08-16	12:00		1	1
R5012	Placebo	"Abrasion - Nose (Car Accident)" Excoriation Injury, Poisoning And Procedural Complications	2009-08-07	UNK/	No	1/	1/
			2009-08	UNK		1	1
		"Multiple Fractures Right Ankle (Car Accident)" Multiple Fractures Injury, Poisoning And Procedural Complications	2009-08-07	UNK/	Yes	3/	2/
			2009-11-11	UNK		1	1
R5013	Active	"Nausea" Nausea Gastrointestinal Disorders	2009-07-15	10:00/	No	1/	1/
			2009-07-15	10:02		3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R5014	Placebo	"Upper Respiratory Infection"	2009-08-07	09:00/	No	1/	2/
		Upper Respiratory Tract Infection	2009-08-09	11:00			
		Infections And Infestations					
R5014	Placebo	"Toothache"	2009-08-09	06:00/	No	1/	2/
		Toothache	2009-08-11	23:00			
		Gastrointestinal Disorders					
R5014	Placebo	"Upper Respiratory Infection"	2009-09-02	20:00/	No	1/	2/
		Upper Respiratory Tract Infection	2009-09-06	22:00			
		Infections And Infestations					
R5015	Placebo	"Intermittent Headaches"	2009-07-14	19:00/	No	1/	2/
		Headache	2010-09-14	UNK			
		Nervous System Disorders				3	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R5015	Placebo	"Dyspepsia"	2009-07-17	12:00/	No	1/	2/
		Dyspepsia	2009-07-17	13:00		2	1
		Gastrointestinal Disorders					
R5016	Placebo	"Upper Respiratory Infection"	2009-08-12	14:00/	No	1/	2/
		Upper Respiratory Tract Infection	2009-09-02	09:00		1	1
		Infections And Infestations					
		"Oral Thrush"	2009-10-15	08:00/		1/	2/
		Oral Candidiasis	2009-10-17	09:30			
		Infections And Infestations					
"Oral Thrush"	2009-10-17	09:30/	No	2/	2/		
Oral Candidiasis	2009-11-14	09:00		1	1		
Infections And Infestations							

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R5017	Active	"Hypertension" Hypertension Vascular Disorders	2009-10 ONGOING	UNK/	No	2/ 1	2/ 3
R5018		"NONE"					
R5019	Placebo	"Oral Dryness" Dry Mouth Gastrointestinal Disorders	2009-08-12 2009-10-23	14:00/ 06:00	No	1/ 4	1/ 1
R5020		"NONE"					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>					
			Date	Time								
R5021	Placebo	"Headache"	2009-07-22	10:00/	No	1/	1/					
		Headache	2009-07-24	08:00				3	1			
		Nervous System Disorders										
		"Dyspepsia"	2009-07-22	10:00/				No	1/	1/		
		Dyspepsia	2009-07-24	08:00							2	1
		Gastrointestinal Disorders										
"Headache"	2009-09-08	17:00/	No	1/	2/							
Headache	2009-09-09	07:00				1	1					
Nervous System Disorders												
R5022		"NONE"										

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R5023	Active	"Burning Sensation To Gums" Gingival Pain Gastrointestinal Disorders	2009-07-24	13:00/	No	1/	1/
			2009-11-16	10:00		5	1
R5024		"Insomnia" Insomnia Psychiatric Disorders	2009-08-05	23:00/	No	1/	1/
			2009-09-17	22:00		2	1
R5025	Placebo	"Nausea" Nausea Gastrointestinal Disorders	2009-07-28	UNK/ 14:00	No	1/ 3	1/ 1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R5025	Placebo	"Upper Respiratory Infection" Upper Respiratory Tract Infection Infections And Infestations	2009-11-15	09:30/	No	1/	1/
			2009-11-16	10:00		1	1
R5026		"NONE"					
R5027	Active	"Irritation Inner Upper Lip" Cheilitis Gastrointestinal Disorders	2009-07-30	14:00/	No	1/	1/
			2009-08-05	08:00		3	1
		"Bleeding From Left Ear Canal" Ear Haemorrhage Ear And Labyrinth Disorders	2009-07-31	10:30/	No	1/	1/
			2009-07-31	11:30		1	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R5027	Active	"Pregnancy"	2009-12-13	UNK/	Yes	1/	5/
		Pregnancy Pregnancy, Puerperium And Perinatal Conditions	ONGOING			1	3
R5028	Active	"Nausea"	2009-07-29	UNK/	No	1/	1/
		Nausea	2009-07-30	14:30		4	1
		"Gum Sensitivity"	2009-07-29	UNK/		1/	1/
		Gingival Pain Gastrointestinal Disorders	2009-08-10	08:00		3	1
		"Flu"	2009-08-05	00:00/	No	1/	2/
		Influenza Infections And Infestations	2009-09-22	22:00		1	1

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R5028	Active	"Cough"	2009-08-12	13:45/	No	1/	1/
		Cough	2009-08-20	13:45		1	1
		Respiratory, Thoracic And Mediastinal Disorders					
		"Teeth Sensitivity"	2009-08-17	08:00/	No	1/	1/
Sensitivity Of Teeth	2009-08-17	08:15	3	1			
Gastrointestinal Disorders							
"Teeth Sensitivity"	2009-08-25	08:00/	No	1/	1/		
Sensitivity Of Teeth	2009-08-31	08:00		3	1		
Gastrointestinal Disorders							
"Upset Stomach"	2009-09-24	08:00/	No	1/	1/		
Stomach Discomfort	2009-10-15	UNK		3	1		
Gastrointestinal Disorders							

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.

Listing 16.2.7-1 Adverse Events by Subject

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Study Population: ITT

Subject Number	Study Product Prior to Onset	"Verbatim Term" Preferred Term System Organ Class	Onset/ Resolved/Changed		Serious?	Severity <sup>a</sup> / RTP <sup>b</sup>	Action <sup>c</sup> / Outcome <sup>d</sup>
			Date	Time			
R5028	Active	"Vomiting"	2009-10-05	16:30/	No	1/	1/
		Vomiting	2009-10-05	16:32		4	1
		Gastrointestinal Disorders					
		"Upper Respiratory Infection"	2009-12-12	05:45/	No	1/	2/
Upper Respiratory Tract Infection	2009-12-17	07:30	1	1			
		Infections And Infestations					

NOTE: Adverse Events were coded using MedDRA (Version 11.1); UNK=UNKNOWN.

<sup>a</sup> Severity: 1=Mild, 2=Moderate, 3=Severe.

<sup>b</sup> Relationship to Study Product: 1=Not Related, 2=Unlikely, 3=Possibly Related, 4=Probably Related, 5=Definitely Related.

<sup>c</sup> Action Taken: 1=None, 2=Other Drug Therapy, 3=Other Treatment or Procedure, 4=Discontinuation of Drug Therapy, 5=Discontinuation from Study.

<sup>d</sup> Outcome: 1=Recovered, 2=Continuing without Treatment, 3=Continuing with Treatment, 4=Death.