

Tabulated Results Addendum: Non Serious Adverse Events not reported in tabulated results due to an identified EudraCT system issue (tracked as issue: ECTRESIII-1916)

Non-Serious Adverse Events	Open Label CNV1014802	Double Blind CNV1014802	Double Blind Placebo
	N=67	N=15	N=14
Gastrointestinal Disorders			
Abdominal discomfort			
Subjects affected/exposed	1/67	0/15	0/14
Occurrences (all)	2	0	0
Abdominal pain			
Subjects affected/exposed	1/67	0/15	1/14
Occurrences (all)	1	0	1
Dry mouth			
Subjects affected/exposed	1/67	0/15	0/14
Occurrences (all)	2	0	0
Enterocoele			
Subjects affected/exposed	0/67	0/15	1/14
Occurrences (all)	0	0	1
Gastrointestinal sounds abnormal			
Subjects affected/exposed	1/67	0/15	0/14
Occurrences (all)	1	0	0
Gingival disorder			
Subjects affected/exposed	1/67	0/15	0/14
Occurrences (all)	1	0	0
Melaena			
Subjects affected/exposed	1/67	0/15	0/14
Occurrences (all)	1	0	0
Nausea			
Subjects affected/exposed	1/67	0/15	0/14
Occurrences (all)	1	0	0
Oral pruritis			
Subjects affected/exposed	1/67	0/15	0/14
Occurrences (all)	1	0	0
Toothache			
Subjects affected/exposed	0/67	1/15	0/14

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Occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia			
Subjects affected/exposed	1/67	0/15	0/14
Occurrences (all)	1	0	0
Chills			
Subjects affected/exposed	1/67	0/15	0/14
Occurrences (all)	1	0	0
Thirst			
Subjects affected/exposed	1/67	0/15	0/14
Occurrences (all)	1	0	0
Eye disorders			
Diplopia			
Subjects affected/exposed	1/67	0/15	0/14
Occurrences (all)	1	0	0
Visual impairment			
Subjects affected/exposed	1/67	0/15	0/14
Occurrences (all)	1	0	0
Nervous system disorders			
Memory impairment			
Subjects affected/exposed	2/67	0/15	0/14
Occurrences (all)	2	0	0
Somnolence			
Subjects affected/exposed	2/67	0/15	0/14
Occurrences (all)	2	0	0
Tremor			
Subjects affected/exposed	1/67	1/15	0/14
Occurrences (all)	1	1	0
Psychiatric disorders			
Abnormal dreams			
Subjects affected/exposed	1/67	0/15	0/14
Occurrences (all)	1	0	0
Depression			
Subjects	1/67	0/15	0/14

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affected/exposed			
Occurrences (all)	1	0	0
Insomnia			
Subjects affected/exposed	1/67	0/15	1/14
Occurrences (all)	1	0	1
Restlessness			
Subjects affected/exposed	1/67	0/15	0/14
Occurrences (all)	1	0	0

In reference to EudraCT #: 2010-023963-16

Threshold: 0%

Dictionary name/version: MedDRA/14.1

Addendum associated with tabulated results version #1.