

Supplemental Table 1. Commonly Reported TEAEs ($\geq 5\%$ of Patients in Either Group or $\geq 3\%$ of Patients With a GI Disorder) Categorized by Male Sex

System Organ Class (Preferred Term, MedDRA 19.1)	Lubiprostone 12 mcg BID (n=24), n (%)	Lubiprostone 24 mcg BID (n=14), n (%)	Total (N=38), N (%)
Patients with ≥ 1 TEAE	11 (45.8)	5 (35.7)	16 (42.1)
Gastrointestinal disorders	5 (20.8)	3 (21.4)	8 (21.1)
Diarrhea	2 (8.3)	1 (7.1)	3 (7.9)
Abdominal pain upper	1 (4.2)	1 (7.1)	2 (5.3)
Dyspepsia	2 (8.3)	0 (0.0)	2 (5.3)
Vomiting	1 (4.2)	1 (7.1)	2 (5.3)
Abdominal distension	1 (4.2)	0 (0.0)	1 (2.6)
Abdominal pain	1 (4.2)	0 (0.0)	1 (2.6)
Abdominal tenderness	1 (4.2)	0 (0.0)	1 (2.6)
Fecaloma	1 (4.2)	0 (0.0)	1 (2.6)
Flatulence	1 (4.2)	0 (0.0)	1 (2.6)
Nausea	0 (0.0)	1 (7.1)	1 (2.6)
Injury, poisoning, and procedural complications	2 (8.3)	1 (7.1)	3 (7.9)
Thermal burn	0 (0.0)	1 (7.1)	1 (2.6)
Investigations	2 (8.3)	2 (14.3)	4 (10.5)
Blood uric acid decreased	2 (8.3)	0 (0.0)	2 (5.3)
Blood iron decreased	0 (0.0)	1 (7.1)	1 (2.6)
Blood phosphorus increased	0 (0.0)	1 (7.1)	1 (2.6)
Heart rate irregular	0 (0.0)	1 (7.1)	1 (2.6)
Specific gravity urine increased	0 (0.0)	1 (7.1)	1 (2.6)
Musculoskeletal and connective tissue disorders	1 (4.2)	1 (7.1)	2 (5.3)
Neck pain	0 (0.0)	1 (7.1)	1 (2.6)
Renal and urinary disorders	0 (0.0)	1 (7.1)	1 (2.6)
Urine abnormality	0 (0.0)	1 (7.1)	1 (2.6)

BID = twice daily; GI = gastrointestinal; MedDRA = Medical Dictionary for Regulatory Activities; N = total population; n = subgroup of total population; TEAE = treatment-emergent adverse event.