

Supplemental Table 8. Commonly Reported TEAEs ($\geq 5\%$ of Patients in Either Group or $\geq 3\%$ of Patients With a GI Disorder) Categorized by Age Group 14 to 17 Years

System Organ Class (Preferred Term, MedDRA 19.1)	Lubiprostone 12 mcg BID (n=1), n (%)	Lubiprostone 24 mcg BID (n=14), n (%)	Total (N=15), N (%)
Patients with ≥ 1 TEAE	1 (100.0)	7 (50.0)	8 (53.3)
Gastrointestinal disorders	0 (0.0)	4 (28.6)	4 (26.7)
Abdominal pain upper	0 (0.0)	2 (14.3)	2 (13.3)
Diarrhea	0 (0.0)	2 (14.3)	2 (13.3)
Colitis ulcerative	0 (0.0)	1 (7.1)	1 (6.7)
Infections and infestations	0 (0.0)	1 (7.1)	1 (6.7)
Viral upper respiratory tract infection	0 (0.0)	1 (7.1)	1 (6.7)
Injury, poisoning, and procedural complications	0 (0.0)	1 (7.1)	1 (6.7)
Thermal burn	0 (0.0)	1 (7.1)	1 (6.7)
Investigations	1 (100.0)	4 (28.6)	5 (33.3)
Blood triglycerides increased	1 (100.0)	1 (7.1)	2 (13.3)
Blood cholesterol increased	0 (0.0)	1 (7.1)	1 (6.7)
Blood iron decreased	0 (0.0)	1 (7.1)	1 (6.7)
Blood phosphorus increased	0 (0.0)	1 (7.1)	1 (6.7)
Heart rate irregular	0 (0.0)	1 (7.1)	1 (6.7)
Red blood cells urine positive	0 (0.0)	1 (7.1)	1 (6.7)
Specific gravity urine increased	0 (0.0)	1 (7.1)	1 (6.7)
Metabolism and nutrition disorders	0 (0.0)	1 (7.1)	1 (6.7)
Decreased appetite	0 (0.0)	1 (7.1)	1 (6.7)

Hypokalemia	0 (0.0)	1 (7.1)	1 (6.7)
Musculoskeletal and connective tissue disorders	0 (0.0)	2 (14.3)	2 (13.3)
Arthralgia	0 (0.0)	1 (7.1)	1 (6.7)
Back pain	0 (0.0)	1 (7.1)	1 (6.7)
Neck pain	0 (0.0)	1 (7.1)	1 (6.7)
Renal and urinary disorders	1 (100.0)	1 (7.1)	2 (13.3)
Urine abnormality	1 (100.0)	1 (7.1)	2 (13.3)
Respiratory, thoracic, and mediastinal disorders	0 (0.0)	1 (7.1)	1 (6.7)
Cough	0 (0.0)	1 (7.1)	1 (6.7)

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