

Supplemental Table 7. Commonly Reported TEAEs ($\geq 5\%$ of Patients in Either Group or $\geq 3\%$ of Patients With a GI Disorder) Categorized by Age Group 10 to 13 Years

System Organ Class (Preferred Term, MedDRA 19.1)	Lubiprostone 12 mcg BID (n=16), n (%)	Lubiprostone 24 mcg BID (n=14), n (%)	Total (N=30), N (%)
Patients with ≥ 1 TEAE	7 (43.8)	7 (50.0)	14 (46.7)
Gastrointestinal disorders	3 (18.8)	5 (35.7)	8 (26.7)
Diarrhea	3 (18.8)	1 (7.1)	4 (13.3)
Abdominal pain	0 (0.0)	2 (14.3)	2 (6.7)
Vomiting	0 (0.0)	2 (14.3)	2 (6.7)
Abdominal distension	1 (6.3)	0 (0.0)	1 (3.3)
Abdominal pain upper	1 (6.3)	0 (0.0)	1 (3.3)
Anal fissure	0 (0.0)	1 (7.1)	1 (3.3)
Aphthous ulcer	0 (0.0)	1 (7.1)	1 (3.3)
Constipation	0 (0.0)	1 (7.1)	1 (3.3)
Dyspepsia	1 (6.3)	0 (0.0)	1 (3.3)
Fecaloma	0 (0.0)	1 (7.1)	1 (3.3)
Gastroesophageal reflux disease	0 (0.0)	1 (7.1)	1 (3.3)
General disorders and administration site conditions	2 (12.5)	0 (0.0)	2 (6.7)
Chest discomfort	1 (6.3)	0 (0.0)	1 (3.3)
Peripheral swelling	1 (6.3)	0 (0.0)	1 (3.3)
Pyrexia	1 (6.3)	0 (0.0)	1 (3.3)
Immune system disorders	1 (6.3)	1 (7.1)	2 (6.7)
Allergy to arthropod bite	1 (6.3)	0 (0.0)	1 (3.3)

Anaphylactoid reaction	0 (0.0)	1 (7.1)	1 (3.3)
Infections and infestations	2 (12.5)	2 (14.3)	4 (13.3)
Pharyngitis streptococcal	1 (6.3)	1 (7.1)	2 (6.7)
Sinusitis	0 (0.0)	1 (7.1)	1 (3.3)
Urinary tract infection	1 (6.3)	0 (0.0)	1 (3.3)
Injury, poisoning, and procedural complications	1 (6.3)	0 (0.0)	1 (3.3)
Vascular injury	1 (6.3)	0 (0.0)	1 (3.3)
Investigations	2 (12.5)	4 (28.6)	6 (20.0)
Alanine aminotransferase increased	0 (0.0)	1 (7.1)	1 (3.3)
Blood cholesterol increased	0 (0.0)	1 (7.1)	1 (3.3)
Blood iron decreased	0 (0.0)	1 (7.1)	1 (3.3)
Blood iron increased	1 (6.3)	0 (0.0)	1 (3.3)
Blood thyroid-stimulating hormone increased	0 (0.0)	1 (7.1)	1 (3.3)
Glycosylated hemoglobin increased	0 (0.0)	1 (7.1)	1 (3.3)
Urine analysis abnormal	1 (6.3)	0 (0.0)	1 (3.3)
Metabolism and nutrition disorders	0 (0.0)	1 (7.1)	1 (3.3)
Hypertriglyceridemia	0 (0.0)	1 (7.1)	1 (3.3)
Impaired fasting glucose	0 (0.0)	1 (7.1)	1 (3.3)
Nervous system disorders	2 (12.5)	1 (7.1)	3 (10.0)
Headache	1 (6.3)	1 (7.1)	2 (6.7)
Syncope	1 (6.3)	0 (0.0)	1 (3.3)
Respiratory, thoracic, and mediastinal disorders	2 (12.5)	1 (7.1)	3 (10.0)

Asthma exercise induced	0 (0.0)	1 (7.1)	1 (3.3)
Epistaxis	1 (6.3)	0 (0.0)	1 (3.3)
Rhinorrhea	1 (6.3)	0 (0.0)	1 (3.3)
Skin and subcutaneous tissue disorders	2 (12.5)	1 (7.1)	3 (10.0)
Dermatitis contact	1 (6.3)	0 (0.0)	1 (3.3)
Pruritus	1 (6.3)	0 (0.0)	1 (3.3)
Rash	0 (0.0)	1 (7.1)	1 (3.3)

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