

Supplemental Table 2. Commonly Reported TEAEs ($\geq 5\%$ of Patients in Either Group or $\geq 3\%$ of Patients With a GI Disorder) Categorized by Female Sex

System Organ Class (Preferred Term, MedDRA 19.1)	Lubiprostone 12 mcg BID (n=32), n (%)	Lubiprostone 24 mcg BID (n=17), n (%)	Total (N=49), N (%)
Patients with ≥ 1 TEAE	21 (65.6)	10 (58.8)	31 (63.3)
Gastrointestinal disorders	8 (25.0)	7 (41.2)	15 (30.6)
Diarrhea	3 (9.4)	2 (11.8)	5 (10.2)
Nausea	4 (12.5)	0 (0.0)	4 (8.2)
Vomiting	2 (6.3)	2 (11.8)	4 (8.2)
Abdominal pain	0 (0.0)	2 (11.8)	2 (4.1)
Abdominal pain upper	0 (0.0)	1 (5.9)	1 (2.0)
Anal fissure	0 (0.0)	1 (5.9)	1 (2.0)
Aphthous ulcer	0 (0.0)	1 (5.9)	1 (2.0)
Colitis ulcerative	0 (0.0)	1 (5.9)	1 (2.0)
Constipation	0 (0.0)	1 (5.9)	1 (2.0)
Fecaloma	0 (0.0)	1 (5.9)	1 (2.0)
Gastroesophageal reflux disease	0 (0.0)	1 (5.9)	1 (2.0)
Oral contusion	1 (3.1)	0 (0.0)	1 (2.0)
General disorders and administration site conditions	4 (12.5)	0 (0.0)	4 (8.2)
Pyrexia	2 (6.3)	0 (0.0)	2 (4.1)
Immune system disorders	0 (0.0)	1 (5.9)	1 (2.0)
Anaphylactoid reaction	0 (0.0)	1 (5.9)	1 (2.0)
Infections and infestations	6 (18.8)	3 (17.6)	9 (18.4)
Pharyngitis streptococcal	2 (6.3)	1 (5.9)	3 (6.1)
Gastroenteritis viral	2 (6.3)	0 (0.0)	2 (4.1)
Sinusitis	1 (3.1)	1 (5.9)	2 (4.1)
Viral upper respiratory tract infection	0 (0.0)	1 (5.9)	1 (2.0)

Investigations	8 (25.0)	6 (35.3)	14 (28.6)
Blood iron decreased	3 (9.4)	1 (5.9)	4 (8.2)
Blood triglycerides increased	2 (6.3)	1 (5.9)	3 (6.1)
Blood cholesterol increased	0 (0.0)	2 (11.8)	2 (4.1)
Blood iron increased	2 (6.3)	0 (0.0)	2 (4.1)
Urine analysis abnormal	2 (6.3)	0 (0.0)	2 (4.1)
Alanine aminotransferase increased	0 (0.0)	1 (5.9)	1 (2.0)
Blood thyroid-stimulating hormone increased	0 (0.0)	1 (5.9)	1 (2.0)
Glycosylated hemoglobin increased	0 (0.0)	1 (5.9)	1 (2.0)
Red blood cells urine positive	0 (0.0)	1 (5.9)	1 (2.0)
Metabolism and nutrition disorders	1 (3.1)	2 (11.8)	3 (6.1)
Decreased appetite	1 (3.1)	1 (5.9)	2 (4.1)
Hypertriglyceridemia	0 (0.0)	1 (5.9)	1 (2.0)
Hypokalemia	0 (0.0)	1 (5.9)	1 (2.0)
Impaired fasting glucose	0 (0.0)	1 (5.9)	1 (2.0)
Musculoskeletal and connective tissue disorders	0 (0.0)	1 (5.9)	1 (2.0)
Arthralgia	0 (0.0)	1 (5.9)	1 (2.0)
Back pain	0 (0.0)	1 (5.9)	1 (2.0)
Nervous system disorders	3 (9.4)	1 (5.9)	4 (8.2)
Headache	3 (9.4)	1 (5.9)	4 (8.2)
Renal and urinary disorders	2 (6.3)	0 (0.0)	2 (4.1)
Urine abnormality	2 (6.3)	0 (0.0)	2 (4.1)
Respiratory, thoracic, and mediastinal disorders	4 (12.5)	2 (11.8)	6 (12.2)
Asthma exercise	0 (0.0)	1 (5.9)	1 (2.0)

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Cough	0 (0.0)	1 (5.9)	1 (2.0)
Skin and subcutaneous tissue disorders	4 (12.5)	1 (5.9)	5 (10.2)
Rash	0 (0.0)	1 (5.9)	1 (2.0)

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