

Supplemental Table 4. Commonly Reported TEAEs (≥5% of Patients in Either Group or ≥3% of Patients With a GI Disorder) Categorized by Black Patients

System Organ Class (Preferred Term, MedDRA 19.1)	Lubiprostone 12 mcg BID (n=11), n (%)	Lubiprostone 24 mcg BID (n=5), n (%)	Total (N=16), N (%)
Patients with ≥1 TEAE	4 (36.4)	2 (40.0)	6 (37.5)
Eye disorders	1 (9.1)	0 (0.0)	1 (6.3)
Conjunctivitis allergic	1 (9.1)	0 (0.0)	1 (6.3)
Gastrointestinal disorders	1 (9.1)	2 (40.0)	3 (18.8)
Abdominal pain	1 (9.1)	1 (20.0)	2 (12.5)
Abdominal pain upper	0 (0.0)	1 (20.0)	1 (6.3)
Anal fissure	0 (0.0)	1 (20.0)	1 (6.3)
Colitis ulcerative	0 (0.0)	1 (20.0)	1 (6.3)
Constipation	0 (0.0)	1 (20.0)	1 (6.3)
Fecaloma	0 (0.0)	1 (20.0)	1 (6.3)
Gastroesophageal reflux disease	0 (0.0)	1 (20.0)	1 (6.3)
General disorders and administration site conditions	1 (9.1)	0 (0.0)	1 (6.3)
Chest pain	1 (9.1)	0 (0.0)	1 (6.3)
Pyrexia	1 (9.1)	0 (0.0)	1 (6.3)
Infections and infestations	1 (9.1)	0 (0.0)	1 (6.3)
Sinusitis	1 (9.1)	0 (0.0)	1 (6.3)
Investigations	0 (0.0)	2 (40.0)	2 (12.5)
Blood thyroid-stimulating hormone	0 (0.0)	1 (20.0)	1 (6.3)

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Red blood cells urine positive	0 (0.0)	1 (20.0)	1 (6.3)
Metabolism and nutrition disorders	1 (9.1)	1 (20.0)	2 (12.5)
Decreased appetite	1 (9.1)	1 (20.0)	2 (12.5)
Hypokalemia	0 (0.0)	1 (20.0)	1 (6.3)
Musculoskeletal and connective tissue disorders	0 (0.0)	1 (20.0)	1 (6.3)
Arthralgia	0 (0.0)	1 (20.0)	1 (6.3)
Back pain	0 (0.0)	1 (20.0)	1 (6.3)
Nervous system disorders	2 (18.2)	0 (0.0)	2 (12.5)
Headache	2 (18.2)	0 (0.0)	2 (12.5)
Respiratory, thoracic, and mediastinal disorders	1 (9.1)	1 (20.0)	2 (12.5)
Cough	0 (0.0)	1 (20.0)	1 (6.3)
Nasal congestion	1 (9.1)	0 (0.0)	1 (6.3)
Skin and subcutaneous tissue disorders	0 (0.0)	1 (20.0)	1 (6.3)
Rash	0 (0.0)	1 (20.0)	1 (6.3)

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