

Table 3.22.1
 Number and Percent of Subjects with Treatment-Emergent Gastrointestinal (GI) Adverse Events
 by System Organ Class and Preferred Term
 Pooled Safety Population

System Organ Class Preferred Term	All KRX-0502 [1] (N=301) n(%)	Double-Blind KRX-0502 (N=190) n(%)	Double-Blind Placebo (N=188) n(%)
Any Treatment-Emergent GI AEs [2]	137 (45.5)	94 (49.5)	52 (27.7)
GASTROINTESTINAL DISORDERS	137 (45.5)	94 (49.5)	52 (27.7)
FAECES DISCOLOURED	59 (19.6)	41 (21.6)	0
DIARRHOEA	57 (18.9)	39 (20.5)	23 (12.2)
CONSTIPATION	43 (14.3)	35 (18.4)	19 (10.1)
NAUSEA	22 (7.3)	18 (9.5)	8 (4.3)
ABDOMINAL PAIN	15 (5.0)	9 (4.7)	3 (1.6)
VOMITING	10 (3.3)	8 (4.2)	8 (4.3)
ABDOMINAL DISCOMFORT	8 (2.7)	4 (2.1)	1 (0.5)
FLATULENCE	6 (2.0)	6 (3.2)	3 (1.6)
ABDOMINAL PAIN UPPER	4 (1.3)	3 (1.6)	3 (1.6)
DYSPEPSIA	4 (1.3)	4 (2.1)	1 (0.5)
ABDOMINAL DISTENSION	2 (0.7)	2 (1.1)	1 (0.5)
DRY MOUTH	2 (0.7)	1 (0.5)	1 (0.5)
HAEMATOCHEZIA	2 (0.7)	2 (1.1)	0
HAEMORRHOIDS	2 (0.7)	2 (1.1)	0
COLITIS	1 (0.3)	0	0
COLITIS ISCHAEMIC	1 (0.3)	1 (0.5)	0
DAEFECATION URGENCY	1 (0.3)	1 (0.5)	0
DYSPHAGIA	1 (0.3)	1 (0.5)	0
ENTERITIS	1 (0.3)	1 (0.5)	0
FAECES SOFT	1 (0.3)	0	0

Note: Adverse events are coded using MedDRA version 17.0. A subject is counted once within each system organ class and preferred term.

[1] Includes Study KRX-0502-306 and Study KRX-0502-204 double-blind KRX-0502, Study KRX-0502-306 open-label extension period, and open-label Study KRX-0502-207.

[2] TEAEs are defined as adverse events occurring or worsening in severity after the first dose of study drug. GI events of interest include all adverse events under the MedDRA System Organ Class of Gastrointestinal Disorders.

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GASTROINTESTINAL DISORDERS (cont)			
FOOD POISONING	1 (0.3)	1 (0.5)	0
FREQUENT BOWEL MOVEMENTS	1 (0.3)	1 (0.5)	0
GASTROINTESTINAL HAEMORRHAGE	1 (0.3)	0	0
GASTROESOPHAGEAL REFLUX DISEASE	1 (0.3)	0	3 (1.6)
MUCOUS STOOLS	1 (0.3)	1 (0.5)	0
RECTAL HAEMORRHAGE	1 (0.3)	1 (0.5)	0
TOOTHACHE	1 (0.3)	1 (0.5)	1 (0.5)
UMBILICAL HERNIA	1 (0.3)	1 (0.5)	0
VOMITING PROJECTILE	1 (0.3)	1 (0.5)	0
FAECAL INCONTINENCE	0	0	1 (0.5)
FAECES HARD	0	0	1 (0.5)
GASTRITIS	0	0	1 (0.5)
PANCREATITIS	0	0	1 (0.5)

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