



Annex 1

**Table 1: Information breakdown by suspect drug(s) and indication(s), patient medical history, and loperamide dosage information for the 16 UK spontaneous suspected ADR reports concerning loperamide and cardiac adverse events, initially received by the MHRA between 01 January 2017 and 31 December 2023.**

Report number	Suspect drug(s) and indication(s)	Patient medical history	Loperamide dosage information
1	LOPERAMIDE	-	-
2	LOPERAMIDE AND SIMETHICONE (Euphoric mood)	-	150 DF per day
3	LOPERAMIDE (Gastrointestinal stoma complication)	Drug hypersensitivity	23 ml per day
4	CODEINE (Product used for unknown indication), DIAZEPAM (Product used for unknown indication), LOPERAMIDE (Diarrhoea), LOPERAMIDE AND SIMETHICONE (Diarrhoea), PREGABALIN (Epilepsy, Pain), SERTRALINE (Product used for unknown indication), TRAMADOL (Product used for unknown indication)	Epilepsy, Loss of consciousness, Pain, Seizure, Resuscitation, Substance abuse, Alcohol abuse, Mental disorder, Drug dependence, Drug abuse, Schizophrenia, Mental disorder, Depression, Multiple sclerosis, Seizure, Intentional self-injury, Diarrhoea	-
5	LOPERAMIDE AND SIMETHICONE (Product used for unknown indication), PREGABALIN (Product used for unknown indication)	Seizure	-
6	LOPERAMIDE AND SIMETHICONE (Product used for unknown indication), PREGABALIN (Epilepsy)	Epilepsy	-
7	LOPERAMIDE (Diarrhoea)	-	12 mg QDS
8	LOPERAMIDE (Intentional product misuse)	-	-
9	LOPERAMIDE (Drug withdrawal maintenance therapy)	Drug dependence, Death of relative, Attention deficit hyperactivity disorder, Adams-Stokes syndrome, Arrhythmia, Post-traumatic stress disorder, Long QT syndrome congenital, Suicide attempt, Seizure, Dyskinesia, Palpitations,	30 or 100 mg OD



		Dizziness, Loss of consciousness, Syncope	
10	LOPERAMIDE (Irritable bowel syndrome), METHYLPHENIDATE (Attention deficit hyperactivity disorder)	Irritable bowel syndrome, Attention deficit hyperactivity disorder	2 mg OD
11	LOPERAMIDE AND SIMETHICONE (Ill-defined disorder, Irritable bowel syndrome)	Irritable bowel syndrome, Ill-defined disorder	-
12	LOPERAMIDE AND SIMETHICONE (Depression)	Alcohol use, Anxiety, Depression, Non-tobacco user	-
13	LOPERAMIDE (Depression)	Anxiety, Endotracheal intubation, Extubation, Non-tobacco user, Depression, Brugada syndrome, Alcohol use	-
14	LOPERAMIDE (Depression)	Anxiety, Depression	-
15	LEVETIRACETAM, LOPERAMIDE	-	20 mg QDS
16	LOPERAMIDE (Gastrointestinal stoma complication), OCTREOTIDE (Chylothorax), TRAMETINIB (Chylothorax)	Ileostomy, Hospitalisation, Hypertrophic cardiomyopathy, Intestinal perforation, Congenital cardiovascular anomaly, Noonan syndrome, Gene mutation, Chylothorax	Maximum

Where information has not been reported, a dash is present in the table.