

Appendix 2: Nonserious adverse events reported in randomized controlled trials and observational studies of medical cannabinoid preparations (part 1 of 4)

Adverse event*	Type of study; no. (%) of events	
	Randomized controlled trials n = 4615	Observational studies n = 3553
Blood or lymphatic system disorders	26 (0.6)	0
Anemia	24	0
Leukopenia	2	0
Cardiac disorders	22 (0.5)	107 (3.0)
Palpitations	16	0
Tachycardia	6	107
Eye disorders	106 (2.3)	6 (0.2)
Photopsia	1	0
Blurred vision	105	6
Gastrointestinal disorders	758 (16.4)	558 (15.7)
Abdominal pain	3	2
Constipation	23	14
Diarrhea	45	29
Dry mouth	239	405
Dysphagia	13	0
Glossodynia	1	0
Mouth plaque	0	6
Mouth ulceration	5	4
Nausea	117	29
Oral mucosal disorder	0	12
Oral pain	12	28
Other gastrointestinal tract disorder	285	0
Pharyngitis	0	4
Tooth discolouration	0	11
Vomiting	15	14
General disorders and administration-site conditions	651 (14.1)	42 (1.2)
Application-site irritation	21	0
Asthenia	198	5
Chills	1	0
Edema	0	6
Fatigue	109	19
Feeling abnormal	1	0
Feeling drunk	24	0
Feeling hot	1	0
Hot flush	2	0
Hyperhidrosis	10	0

continued

Appendix 2: Nonserious adverse events reported in randomized controlled trials and observational studies of medical cannabinoid preparations (part 2 of 4)

Adverse event*	Type of study; no. (%) of events	
	Randomized controlled trials <i>n</i> = 4615	Observational studies <i>n</i> = 3553
Influenza	2	0
Instillation-site foreign-body sensation	0	3
Loss of control of legs	0	2
Pain	278	5
Pallor	0	1
Pyrexia	0	1
Tenderness	1	0
Thirst	3	0
Infections and infestations	134 (2.9)	0
Infection	134	0
Injury, poisoning and procedural complications	37 (0.8)	7 (0.2)
Drug toxicity	2	0
Fall	34	0
Joint injury	1	0
Poisoning	0	7
Investigations	1 (< 0.1)	13 (0.4)
γ-Glutamyltransferase increased	0	6
Weight decreased	1	7
Metabolism and nutrition disorders	37 (0.8)	0
Anorexia	5	0
Increased appetite	32	0
Musculoskeletal, connective tissue and bone disorders	331 (7.2)	0
Arthralgia	1	0
Muscle spasm	289	0
Muscle spasticity	5	0
Muscle twitching	21	0
Muscle weakness	4	0
Musculoskeletal pain	2	0
Myalgia	7	0
Sensation of heaviness	2	0
Nervous system disorders	1695 (36.7)	1412 (39.7)
Abnormal dreams	2	0
Balance disorder	13	12
Cholinergic syndrome	0	1
Coordination abnormal	73	185
Dysarthria	0	1

continued

Appendix 2: Nonserious adverse events reported in randomized controlled trials and observational studies of medical cannabinoid preparations (part 3 of 4)

Adverse event*	Type of study; no. (%) of events	
	Randomized controlled trials <i>n</i> = 4615	Observational studies <i>n</i> = 3553
Dizziness	714	393
Dreamy state	16	0
Dysgeusia	22	11
Headache	79	21
Hypoesthesia	28	0
Hypotonia	0	4
Lethargy	0	6
Memory impairment	29	5
Migraine	1	0
Multiple sclerosis	31	5
Nervous system disorder (unspecified)	2	0
Neurologic visual problems not classified elsewhere	0	224
Paraesthesia	63	0
Paralysis	0	2
Sedation	100	517
Sensory disturbance	0	1
Somnolence	377	23
Spasticity	0	1
Syncope	29	0
Tinnitus	29	0
Tremor	71	0
Vertigo	16	0
Psychiatric disorders	512 (11.1)	1265 (35.6)
Abnormal dreams	0	149
Affect liability	3	0
Aggression	4	0
Anxiety	4	214
Confusional state	14	308
Delusional perception	18	0
Depression	93	193
Disorientation	28	0
Dissociation	34	0
Disturbance in attention	28	12
Euphoric mood	127	1
Feeling of despair	7	0
Hallucinations	15	0
Inappropriate affect	1	0

continued

Appendix 2: Nonserious adverse events reported in randomized controlled trials and observational studies of medical cannabinoid preparations (part 4 of 4)

Adverse event*	Type of study; no. (%) of events	
	Randomized controlled trials n = 4615	Observational studies n = 3553
Indifference	4	0
Irritability	5	0
Mental disorder	51	0
Mood altered	24	290
Nervousness	4	0
Panic attack	1	95
Paranoia	1	2
Psychomotor hyperactivity	1	0
Sleep disorder	0	1
Speech disorder	45	0
Renal and urinary disorders	236 (5.1)	0
Bladder disorder	222	0
Urinary tract infection	14	0
Respiratory, thoracic and mediastinal disorders	36 (0.8)	2 (0.1)
Cough	2	0
Dysphonia	1	0
Dyspnea	22	0
Hypoxia	0	1
Nasopharyngitis	4	0
Pharyngitis	4	0
Pulmonary embolism	0	1
Throat irritation	2	0
Upper respiratory tract infection	1	0
Skin or subcutaneous tissue disorders	30 (0.7)	0
Decubitus ulcer	4	0
Pruritus	11	0
Skin problem	15	0
Vascular disorders	3 (0.1)	141 (4.0)
Hypertension	2	0
Hypotension	1	141

*Grouped by system order classes of the *Medical Dictionary for Regulatory Activities*.¹

Reference

1. *Medical dictionary for regulatory activities*. Version 10.0. Los Angeles: Northrop Grumman Corporation; 2008. Available (by subscription): www.meddrmsso.com/ (accessed 2008 Mar 25).