Report Run Date: 17-Oct-2022

Data Lock Date: 14-Oct-2022 18:30:04

Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Drug Analysis Print: with electronic cigarettes up to and including

30/09/2022

#### Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04 Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Blood disorders		
Haematological disorders		
Methaemoglobinaemia	1	0
Blood disorders SOC TOTAL	1	0

Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Oct-2022
Earliest Reaction Date: 01-Jan-2010

Data Lock Date: 14-Oct-2022 18:30:04

MedDRA Version: MedDRA 25.0

Laniest Neaction Date. 01-3an-2010	MCaDIA VCISION, MCaDIA 25.0		
Reaction Name		Total	Fatal
Cardiac disorders			
Cardiac conduction disorders			
Atrioventricular block		1	0
Cardiac disorders NEC			
Cardiovascular disorder		2	0
Cardiac signs and symptoms NEC			
Palpitations		7	0
Endocarditis NEC			
Endocarditis noninfective		1	1
Ischaemic coronary artery disorders			
Angina pectoris		2	0
Rate and rhythm disorders NEC			
Bradycardia		1	0
Tachycardia		1	0
Supraventricular arrhythmias			
Atrial fibrillation		2	0
Supraventricular tachycardia		1	0
Ventricular arrhythmias and cardiac arrest			
Cardiac arrest		3	1
Ventricular extrasystoles		2	0
Ventricular fibrillation		1	0
Ventricular tachycardia		1	0
Cardiac disorders SOC TOTAL		25	2

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Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04 Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Ear disorders		
Inner ear signs and symptoms		
Tinnitus	1	0
Vertigo	3	0
Ear disorders SOC TOTAL	4	0

#### Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Endocrine disorders		
Thyroid hypofunction disorders		
Hypothyroidism	1	0
Endocrine disorders SOC TOTAL	1	l o

Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Oct-2022
Earliest Reaction Date: 01-Jan-2010

Data Lock Date: 14-Oct-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders		
Lacrimation disorders		
Lacrimation increased	2	0
Ocular disorders NEC		
Eye pain	2	0
Ocular infections, inflammations and associated manifestations		
Eye irritation	1	0
Eye pruritus	1	0
Visual disorders NEC		
Vision blurred	1	0
Eve disorders SOC TOTAL	7	0

Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Gastrointestinal disorders		
Dental pain and sensation disorders		
Toothache	1	0
Diarrhoea (excl infective)		
Diarrhoea	3	0
Dyspeptic signs and symptoms		
Dyspepsia	2	0
Faecal abnormalities NEC		
Faeces discoloured	1	0
Flatulence, bloating and distension		
Abdominal distension	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	2	0
Abdominal pain upper	5	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	1	0
Gastrooesophageal reflux disease	3	0
Gastrointestinal signs and symptoms NEC		_
Abdominal discomfort	3	0
Breath odour	1	0
Dysphagia	1	0
Gingival disorders, signs and symptoms NEC	4	
Gingival discomfort	1	0
Gingival erythema	1	0
Gingival page 2	1	0
Gingival recession	1	0
Gingival swelling	2	0
Noninfective gingivitis	1	0
Gingival haemorrhages	2	
Gingival bleeding  Nausea and vomiting symptoms	3	0
Discoloured vomit	1	0
Nausea	21	0
Post-tussive vomiting	1	0
Vomiting	5	0
Oral dryness and saliva altered		
Dry mouth	1	0
Oral soft tissue disorders NEC		Ĭ
Cheilitis	1	0
Oral disorder	1	o
Oral soft tissue haemorrhages		
Mouth haemorrhage	1	0
Oral soft tissue signs and symptoms		
Coating in mouth	1	0
Hypoaesthesia oral	1	0
Oral discomfort	4	0
Oral mucosal blistering	2	0
Oral mucosal erythema	1	0
Oral pain	1	0
Paraesthesia oral	2	0
Oral soft tissue swelling and oedema		
Lip swelling	2	0
Mouth swelling	3	0
Stomatitis and ulceration		

Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04 Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Gastrointestinal disorders cont'd		
Aphthous ulcer		1 0
Mouth ulceration		6 0
Stomatitis		4 0
Tongue disorders		
Glossitis		1 0
Tongue signs and symptoms		
Swollen tongue	;	3 0
Tongue discomfort		2 0
Tongue eruption		1 0
Gastrointestinal disorders SOC TOTAL	10	1 0

Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders	10.01	<u> </u>
Asthenic conditions		
Asthenia	1	0
Fatigue	7	0
Malaise	11	0
Febrile disorders		
Pyrexia	4	0
Feelings and sensations NEC		
Chills	1	0
Feeling abnormal	3	0
Feeling cold	1	0
Feeling hot	2	0
Feeling of body temperature change	1	0
Fibrosis NEC		
Fibrosis	1	0
General signs and symptoms NEC		
Condition aggravated	4	0
Exercise tolerance decreased	1	0
Influenza like illness	2	0
Swelling	2	0
Swelling face	1	0
Inflammations		
Inflammation	2	0
Interactions		
Drug interaction	4	0
Oedema NEC		
Oedema	1	0
Pain and discomfort NEC		
Chest discomfort	17	0
Chest pain	25	0
Discomfort	1	0
Non-cardiac chest pain	5	0
Pain	1	0
Therapeutic and nontherapeutic responses		
Drug tolerance	1	0
General disorders SOC TOTAL	99	0

Name: Electronic Cigarette Drug Analysis Print
17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04
Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0 Report Run Date: 17-Oct-2022 Earliest Reaction Date: 01-Jan-2010

Reaction Name	Total	Fatal
Hepatic disorders		
Hepatocellular damage and hepatitis NEC		
Liver injury	1	0
Hepatic disorders SOC TOTAL	1	0

Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04 Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Hypersensitivity	8	0
Allergies to foods, food additives, drugs and other chemicals		
Reaction to excipient	8	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	1	0
Anaphylactic shock	1	0
Immune and associated conditions NEC		
Immune system disorder	1	0
Immune system disorders SOC TOTAL	19	0

Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
Coronavirus infections		
Severe acute respiratory syndrome	1	0
Ear infections		
Ear infection	1	0
Lower respiratory tract and lung infections		
Bronchitis	2	0
Infectious pleural effusion	1	0
Pneumonia	3	0
Upper respiratory tract infections		
Croup infectious	1	0
Pharyngitis	1	0
Rhinitis	3	0
Sinusitis	4	0
Infections SOC TOTAL	17	0

Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Oct-2022
Earliest Reaction Date: 01-Jan-2010

Data Lock Date: 14-Oct-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Injuries		
Non-occupational environmental exposures		
Environmental exposure	12	0
Product administration errors and issues		
Accidental overdose	1	0
Expired product administered	1	0
Incorrect route of product administration	1	0
Thermal burns		
Airway burns	1	0
Thermal burn	1	0
Injuries SOC TOTAL	17	0

Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Oct-2022
Earliest Reaction Date: 01-Jan-2010

Data Lock Date: 14-Oct-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations		
Heart rate and pulse investigations		
Heart rate decreased	1	0
Heart rate increased	1	0
Hepatobiliary function diagnostic procedures		
Gamma-glutamyltransferase increased	1	0
Physical examination procedures and organ system status		
Body temperature abnormal	1	0
Breath sounds abnormal	1	0
Weight decreased	1	0
Respiratory and pulmonary function diagnostic procedures		
Total lung capacity decreased	1	0
Therapeutic drug monitoring analyses		
Antipsychotic drug level increased	1	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	1	0
Investigations SOC TOTAL	9	0

Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	1	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	1	0
Hyperglycaemia	1	0
Mixed acid-base disorders		
Acidosis	1	0
Metabolic disorders SOC TOTAL	4	0

Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04 Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Joint related signs and symptoms		
Arthralgia	3	0
Muscle pains		
Myalgia	2	0
Muscle related signs and symptoms NEC		
Muscle spasms	1	0
Muscle tightness	2	0
Muscle twitching	1	0
Musculoskeletal and connective tissue conditions NEC		
Musculoskeletal stiffness	1	0
Musculoskeletal and connective tissue pain and discomfort		
Musculoskeletal chest pain	2	0
Neck pain	1	0
Pain in extremity	1	0
Muscle & tissue disorders SOC TOTAL	14	l o

Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Oct-2022
Earliest Reaction Date: 01-Jan-2010

Data Lock Date: 14-Oct-2022 18:30:04
MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Nervous system disorders	I Olai	Гацаі
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebral infarction	1	C
Subarachnoid haemorrhage	1	
Disturbances in consciousness NEC	'	
Lethargy	3	C
Loss of consciousness	1	
Somnolence	2	C
Syncope	1	
Encephalopathies NEC	i i	
Posterior reversible encephalopathy syndrome	1	C
Headaches NEC	i i	
Cluster headache	1	C
Headache	16	Č
Medication overuse headache	1	Č
Tension headache	1	C
Memory loss (excl dementia)		
Memory impairment	1	C
Mental impairment (excl dementia and memory loss)		
Disturbance in attention	1	C
Migraine headaches		
Migraine	2	C
Neurological signs and symptoms NEC		
Dizziness	17	C
Dizziness postural	1	C
Head discomfort	1	C
Presyncope	2	C
Slow response to stimuli	1	C
Neuromuscular disorders NEC		
Muscle contractions involuntary	1	C
Paraesthesias and dysaesthesias		
Burning sensation	3	(
Paraesthesia	2	C
Seizures and seizure disorders NEC		
Epilepsy	2	(
Seizure	2	(
Sensory abnormalities NEC		
Dysgeusia	2	(
Tremor (excl congenital)		
Tremor	1	(
Nervous system disorders SOC TOTAL	68	

Name: Electronic Cigarette Drug Analysis Print

: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04
Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0 Report Run Date: 17-Oct-2022 Earliest Reaction Date: 01-Jan-2010

Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	1	0
Pregnancy conditions SOC TOTAL	1	0

Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04 Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Reaction Name	<u>Total</u>	Fatal
Product label issues		
Product expiration date issue		1 0
Product label on wrong product		1 0
Product physical issues		
Liquid product physical issue		1 0
Product colour issue		1 0
Product leakage		1 0
Product odour abnormal	4	4 O
Product physical issue	(	6 0
Product taste abnormal	14	4 0
Product quality issues NEC		
Product substitution issue		1 0
Suspected product quality issue		1 0
null SOC TOTAL	3.	1l ol

Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Psychiatric disorders	1 0 10.	
Anxiety disorders NEC		
Anxiety disorder	1	0
Cognitive and attention disorders and disturbances NEC		
Mental fatigue	1	0
Confusion and disorientation		
Confusional state	2	0
Depressive disorders		
Depression	1	0
Disturbances in initiating and maintaining sleep		
Insomnia	1	0
Emotional and mood disturbances NEC		
Anger	1	0
Hallucinations (excl sleep-related)		
Hallucination	1	0
Mood disorders NEC		
Laziness	1	0
Panic attacks and disorders		
Panic attack	1	0
Substance related and addictive disorders		
Dependence	1	0
Psychiatric disorders SOC TOTAL	11	0

Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDR	A 25.0	
Reaction Name	Total	<u>Fatal</u>
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	46	0
Dyspnoea at rest	2	. 0
Dyspnoea exertional	1	0
Respiration abnormal	1	0
Respiratory distress	2	
Tachypnoea	3	0
Bronchospasm and obstruction		
Asthma	9	0
Bronchial hyperreactivity	1	0
Chronic obstructive pulmonary disease	1	0
Wheezing	13	
Conditions associated with abnormal gas exchange		
Asphyxia	1	0
Нурохіа	4	
Coughing and associated symptoms		
Cough	97	0
Haemoptysis	6	
Productive cough	6	1
Sputum increased		0
Lower respiratory tract inflammatory and immunologic conditions		
Alveolitis	1	0
Diffuse alveolar damage	1	
Hypersensitivity pneumonitis	3	
Pneumonia lipoid	3	1
Pneumonitis	3	0
Lower respiratory tract signs and symptoms		
Hiccups	2	0
Lung opacity	3	ő
Pleuritic pain	3	Ö
Pulmonary pain	4	
Rales	1	
Rhonchi	1	
Mediastinal disorders		
Pneumomediastinum	1	0
Nasal congestion and inflammations		
Nasal congestion	3	0
Nasal disorders NEC		
Epistaxis	3	0
Nasal dryness	2	el o
Parenchymal lung disorders NEC		
Cystic lung disease	1	0
Emphysema	1	1
Idiopathic pulmonary fibrosis	1	1
Interstitial lung disease	2	0
Lung consolidation	3	0
Organising pneumonia		
Probable e-cigarette or vaping product use associated lung injury	v 2	Ö
Pulmonary air leakage	, l	_
Pulmonary alveolar haemorrhage	3	_
Pulmonary fibrosis	1	Ö
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal disorder	1	0

Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0	Tatal	Fatal
Reaction Name	Total	Fatal
Respiratory disorders cont'd		0
Pharyngeal swelling	2	0
Pleural conditions NEC		
Bronchopleural fistula	1	0
Pleural adhesion	1	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	3	0
Pneumothorax	3	0
Pneumothorax spontaneous	1	0
Pulmonary oedemas		
Acute lung injury	7	1
Acute respiratory distress syndrome	3	0
Pulmonary congestion	2	0
Pulmonary oedema	1	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	1	0
Respiratory failures (excl neonatal)		
Respiratory failure	2	0
Respiratory tract disorders NEC		
Allergic respiratory disease	1	0
Lung disorder	2	0
Respiratory disorder	2	0
Respiratory tract irritation	2	0
Upper respiratory tract signs and symptoms		
Aphonia	1	0
Catarrh	1	0
Choking	2	0
Dry throat	2	0
Dysphonia	4	0
Nasal discomfort	1	0
Oropharyngeal pain	45	0
Rhinalgia	2	0
Rhinorrhoea	4	0
Sneezing	3	0
Throat irritation	28	0
Respiratory disorders SOC TOTAL	372	3

Name: Electronic Cigarette Drug Analysis Print

: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04
Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0 Report Run Date: 17-Oct-2022 Earliest Reaction Date: 01-Jan-2010

Reaction Name	<u>Total</u>	Fatal
Skin disorders		
Angioedemas		
Angioedema	2	0
Apocrine and eccrine gland disorders		
Hyperhidrosis	2	0
Bullous conditions		
Blister	2	0
Dermal and epidermal conditions NEC		
Papule	1	0
Skin discolouration	1	0
Dermatitis and eczema		
Dermatitis allergic	2	2 0
Erythemas		
Erythema	2	2 0
Pruritus NEC		
Pruritus	5	5 O
Rashes, eruptions and exanthems NEC		
Rash	7	' 0
Rash papular	1	0
Skin and subcutaneous conditions NEC		
Skin mass	1	0
Subcutaneous emphysema	1	0
Urticarias		
Urticaria	2	2 0
Skin disorders SOC TOTAL	29	el o

Report Run Date: 17-Oct-2022 Data Lock Date: 14-Oct-2022 18:30:04
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Vascular disorders		
Non-site specific necrosis and vascular insufficiency NEC		
Vasospasm	1	0
Peripheral vascular disorders NEC		
Cyanosis	1	0
Flushing	1	0
Vascular hypertensive disorders NEC		
Hypertension	2	0
Vascular disorders SOC TOTAL	5	0
TOTAL REACTIONS FOR DRUG	836	5
TOTAL REPORTS	298	
TOTAL FATAL OUTCOME REPORTS		5