Report Run Date: 17-Apr-2024

Data Lock Date: 16-Apr-2024 18:30:03

Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

Drug Analysis Print: with electronic cigarettes up to and including

31/03/2024

#### Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

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-Apr-2024
Earliest Reaction Date: 01-Jan-2010

Data Lock Date: 16-Apr-2024 18:30:03
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac conduction disorders		
Atrioventricular block		0
Cardiac disorders NEC		
Cardiovascular disorder	3	3 0
Cardiac signs and symptoms NEC		
Palpitations	11	. 0
Endocarditis NEC		
Endocarditis noninfective	· · · · · · · · · · · · · · · · · · ·	. 1
Heart failures NEC		
Cardiac failure congestive	· · · · · · · · · · · · · · · · · · ·	. 0
Ischaemic coronary artery disorders		
Angina pectoris	2	2 0
Rate and rhythm disorders NEC		
Bradycardia	· · · · · · · · · · · · · · · · · · ·	. 0
Tachycardia	4	<b>↓</b> 0
Supraventricular arrhythmias		
Atrial fibrillation	2	<u>2</u> 0
Supraventricular tachycardia	· · · · · · · · · · · · · · · · · · ·	. 0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	3	3 1
Ventricular extrasystoles	2	<u>2</u> 0
Ventricular fibrillation	· · · · · · · · ·	. 0
Ventricular tachycardia	· · · · · · · · · · · · · · · · · · ·	. 0
Cardiac disorders SOC TOTAL	34	l 2

#### Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

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

: 17-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1 Report Run Date: 17-Apr-2024 Earliest Reaction Date: 01-Jan-2010

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

Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Apr-2024
Earliest Reaction Date: 01-Jan-2010

Data Lock Date: 16-Apr-2024 18:30:03
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Eye disorders		
Lacrimation disorders		
Lacrimation increased	2	0
Ocular disorders NEC		
Eye pain	3	0
Ocular infections, inflammations and associated manifestations		
Eye irritation	1	0
Eye pruritus	1	0
Visual disorders NEC		
Vision blurred	2	0
Eve disorders SOC TOTAL	9	0

Report Run Date: 17-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Gastrointestinal disorders		
Dental pain and sensation disorders		
Toothache	2	0
Diarrhoea (excl infective)		
Diarrhoea	6	0
Dyspeptic signs and symptoms		
Dyspepsia	3	0
Faecal abnormalities NEC		
Faeces discoloured	1	0
Flatulence, bloating and distension		
Abdominal distension	2	0
Flatulence	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	3	0
Abdominal pain upper	7	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		
Gingival discomfort	1	0
Gingival erythema	1	0
Gingival pain	2	0
Gingival recession	2	0
Gingival swelling	2	0
Noninfective gingivitis	1	0
Gingival haemorrhages		
Gingival bleeding	4	0
Intestinal haemorrhages		
Rectal haemorrhage	1	0
Nausea and vomiting symptoms		
Discoloured vomit	1	0
Nausea	26	0
Post-tussive vomiting	1	0
Vomiting	7	0
Oral dryness and saliva altered		
Dry mouth	2	0
Oral soft tissue disorders NEC		
Cheilitis	1	0
Oral disorder	2	0
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	6	0
Oral mucosal blistering	2	0
Oral mucosal erythema	1	0
Oral pain	2	0
Paraesthesia oral	2	0
Oral soft tissue swelling and oedema		

Report Run Date: 17-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Gastrointestinal disorders cont'd		
Lip swelling	3	0
Mouth swelling	3	0
Stomatitis and ulceration		
Aphthous ulcer	1	0
Mouth ulceration	7	0
Stomatitis	4	0
Tongue disorders		
Glossitis	1	0
Tongue signs and symptoms		
Swollen tongue	3	0
Tongue discomfort	3	0
Tongue eruption	1	0
Gastrointestinal disorders SOC TOTAL	130	0

Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Apr-2024
Earliest Reaction Date: 01-Jan-2010

Data Lock Date: 16-Apr-2024 18:30:03
MedDRA Version: MedDRA 26.1

Reaction Name	MedDRA Version: MedDRA 26.1	Total	Fatal
General disorders		TOlai	Гацаі
Asthenic conditions			
Asthenia Asthenia		1	0
Fatigue		13	0
Malaise		11	0
Febrile disorders		11	U
		c	0
Pyrexia		6	0
Feelings and sensations NEC Chills		4	0
		1	0
Feeling abnormal		2	0
Feeling cold		1	0
Feeling hot		2 1	0
Feeling of body temperature change Fibrosis NEC		1	0
		4	0
Fibrosis		1	0
General signs and symptoms NEC		4	0
Condition aggravated Exercise tolerance decreased		4	0
Influenza like illness		1	0
		2	
Peripheral swelling		1	0
Swelling		2	
Swelling face Inflammations		I	0
Inflammation		2	0
		2	0
Interactions		4	0
Drug interaction Oedema NEC		4	0
		4	0
Oedema Pain and discomfort NEC		I	0
		200	0
Chest discomfort		26	0
Chest pain		30	0
Discomfort		1	0
Non-cardiac chest pain		5	0
Pain		1	0
Therapeutic and nontherapeutic responses		<u>,</u>	^
Drug tolerance		1	0
Therapeutic response unexpected		1	0
General disorders SOC TOTAL		122	0

### Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

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-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Hypersensitivity	10	0
Allergies to foods, food additives, drugs and other chemicals		
Allergic reaction to excipient	1	0
Reaction to excipient	12	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	26	0

Report Run Date: 17-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

Reaction Name	 <u> </u>	Fatal
Infections		
Coronavirus infections		
Severe acute respiratory syndrome	1	0
Ear infections		
Ear infection	1	0
Lower respiratory tract and lung infections		
Bronchitis	3	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	1	0
Pneumonia	5	0
Pneumocystis infections		
Pneumocystis jirovecii pneumonia	1	0
Upper respiratory tract infections		
Croup infectious	1	0
Pharyngitis	2	0
Rhinitis	3	0
Sinusitis	6	0
Infections SOC TOTAL	25	0

Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Apr-2024
Earliest Reaction Date: 01-Jan-2010

Data Lock Date: 16-Apr-2024 18:30:03
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Injuries		
Non-occupational environmental exposures		
Environmental exposure	12	0
Poisoning and toxicity		
Tobacco poisoning	1	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	18	0

Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Apr-2024
Earliest Reaction Date: 01-Jan-2010

Data Lock Date: 16-Apr-2024 18:30:03
MedDRA Version: MedDRA 26.1

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-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

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		<u> </u>

Report Run Date: 17-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

Earliest Reaction Date. 01-Jan-2010	Weddra version. Weddra 26.1		
Reaction Name		Total	Fatal
Muscle & tissue disorders			
Bone related signs and symptoms			
Pain in jaw		1	0
Cartilage disorders			
Costochondritis		1	0
Joint related signs and symptoms			
Arthralgia		3	0
Muscle pains			
Myalgia		2	0
Muscle related signs and symptoms NEC			
Muscle spasms		2	0
Muscle tightness		2	0
Muscle twitching		1	0
Musculoskeletal and connective tissue condi	tions NEC		
Musculoskeletal stiffness		1	0
Musculoskeletal and connective tissue pain a	and discomfort		
Back pain		1	0
Musculoskeletal chest pain		2	0
Neck pain		2	0
Pain in extremity		1	0
Muscle & tissue disorders SOC TOTAL		19	0

### Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Neoplasms		
Laryngeal neoplasms malignant		
Laryngeal cancer	1	0
Neoplasms SOC TOTAL	1	0

Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Apr-2024
Earliest Reaction Date: 01-Jan-2010

Data Lock Date: 16-Apr-2024 18:30:03
MedDRA Version: MedDRA 26.1

Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1	T-4-1	Fatal
Reaction Name	Total	Fatal
Nervous system disorders		
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebral infarction	1	0
Subarachnoid haemorrhage	1	0
Disturbances in consciousness NEC		
Lethargy	4	0
Loss of consciousness	1	0
Somnolence	2	0
Syncope	1	0
Encephalopathies NEC		
Posterior reversible encephalopathy syndrome	1	0
Headaches NEC		
Cluster headache	1	0
Headache	22	0
Medication overuse headache	1	0
Sinus headache	1	0
Tension headache	2	0
Thunderclap headache	1	0
Memory loss (excl dementia)		
Memory impairment	1	0
Mental impairment (excl dementia and memory loss)		
Disturbance in attention	1	0
Migraine headaches		
Migraine	3	0
Neurological signs and symptoms NEC		
Brain fog	1	0
Dizziness	21	0
Dizziness postural	1	0
Head discomfort	1	0
Presyncope	2	0
Slow response to stimuli	1	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	1	0
Paraesthesias and dysaesthesias		
Burning sensation	4	0
Paraesthesia	2	0
Seizures and seizure disorders NEC		
Epilepsy	2	0
Seizure	4	0
Sensory abnormalities NEC		
Dysgeusia	2	0
Tremor (excl congenital)		
Tremor	1	0
Nervous system disorders SOC TOTAL	87	0

Name: Electronic Cigarette Drug Analysis Print

: 17-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1 Report Run Date: 17-Apr-2024 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-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Device issues NEC		
Device leakage	1	0
Product label issues		
Product expiration date issue	1	0
Product label 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		l 0
Product physical issue	6	0
Product taste abnormal	14	l 0
Product quality issues NEC		
Product substitution issue	1	0
Suspected product quality issue	2	0
null SOC TOTAL	34	ŀl o

Report Run Date: 17-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

Reaction Name	Total	<u>Fatal</u>
Psychiatric disorders		
Anxiety disorders NEC		
Anxiety disorder	1	C
Anxiety symptoms		
Anxiety	2	C
Cognitive and attention disorders and disturbances NEC		
Mental fatigue	1	C
Confusion and disorientation		
Confusional state	3	C
Depressive disorders		
Depression	1	C
Depression suicidal	1	C
Disturbances in initiating and maintaining sleep		
Insomnia	1	C
Emotional and mood disturbances NEC		
Anger	1	C
Irritability	1	C
Hallucinations (excl sleep-related)		
Hallucination	1	C
Mood alterations with depressive symptoms		
Depressed mood	1	C
Mood disorders NEC		
Laziness	1	C
Panic attacks and disorders		
Panic attack	1	C
Substance related and addictive disorders		
Dependence	1	C
Nicotine dependence	2	(
Psychiatric disorders SOC TOTAL	19	(

Report Run Date: 17-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	62	0
Dyspnoea at rest	2	0
Dyspnoea exertional	1	0
Respiration abnormal	1	0
Respiratory distress	2	0
Tachypnoea	3	0
Bronchospasm and obstruction		
Asthma	11	0
Bronchial hyperreactivity	1	0
Chronic obstructive pulmonary disease	1	0
Wheezing	16	0
Conditions associated with abnormal gas exchange	10	J
Asphyxia	1	0
Hypoxia	4	0
	4	U
Coughing and associated symptoms	4	
Allergic cough	107	0
Cough		0
Haemoptysis	6	0
Productive cough	9	0
Sputum increased	1	0
Lower respiratory tract inflammatory and immunologic conditions		
Alveolitis	1	0
Diffuse alveolar damage	1	0
Hypersensitivity pneumonitis	3	0
Pneumonia lipoid	3	1
Pneumonitis	3	0
Lower respiratory tract signs and symptoms		
Hiccups	2	0
Lung opacity	4	0
Pleuritic pain	2	0
Pulmonary pain	9	0
Rales	1	0
Rhonchi	1	0
Mediastinal disorders		
Pneumomediastinum	1	0
Nasal congestion and inflammations		
Nasal congestion	3	0
Nasal disorders NEC		
Epistaxis	5	0
Nasal dryness	2	0
Paranasal sinus disorders (excl infections and neoplasms)		
Sinus congestion	1	0
Parenchymal lung disorders NEC	· ·	Ŭ
Confirmed e-cigarette or vaping product use associated lung injury	1	0
Cystic lung disease	1	0
Emphysema	1	0
	1	1
Idiopathic pulmonary fibrosis	2	1
Interstitial lung disease	2	0
Lung consolidation	4	0
Organising pneumonia	2	0
Probable e-cigarette or vaping product use associated lung injury	2	0
Pulmonary air leakage	1	01

Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Apr-2024
Earliest Reaction Date: 01-Jan-2010

Data Lock Date: 16-Apr-2024 18:30:03
MedDRA Version: MedDRA 26.1

Earliest Reaction Date: 01-Jan-2010	MedDRA Version: MedDRA 26.1	
Reaction Name	Total	<u> Fatal</u>
Respiratory disorders cont		
Pulmonary alveolar haemorrhage		3 0
Pulmonary fibrosis		1 0
Pharyngeal disorders (excl infections and r	neoplasms)	
Pharyngeal disorder		1 0
Pharyngeal swelling		5 0
Pleural conditions NEC		
Bronchopleural fistula		1 0
Pleural adhesion		1 0
Pneumothorax and pleural effusions NEC		
Pleural effusion		4 0
Pneumothorax		3 0
Pneumothorax spontaneous		1 0
Pulmonary oedemas		
Acute lung injury		7 1
Acute respiratory distress syndrome		4 0
Pulmonary congestion		2 0 2 0
Pulmonary oedema		2 0
Pulmonary thrombotic and embolic condition	ons	
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 3 0
Respiratory tract irritation		3 0
Upper respiratory tract signs and symptom	s	
Aphonia		1 0
Catarrh		1 0
Choking		2 0
Dry throat		4 0
Dysphonia		4 0
Nasal discomfort		2 0
Oropharyngeal discomfort		1 0
Oropharyngeal pain	4	9 0
Rhinalgia		2 0
Rhinorrhoea		4 0
Sinus pain		1 0
Sneezing		3 0
Throat irritation	3	
Upper-airway cough syndrome		1 0
Respiratory disorders SOC TOTAL	43	

Report Run Date: 17-Apr-2024 Data Lock Date: 16-Apr-2024 18:30:03
Earliest Reaction Date: 01-Jan-2010 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Skin disorders		
Angioedemas		
Angioedema	2	2 0
Apocrine and eccrine gland disorders		
Cold sweat	1	0
Hyperhidrosis	2	2 0
Bullous conditions		
Blister	2	2 0
Dermal and epidermal conditions NEC		
Papule		0
Skin discolouration	1	0
Dermatitis and eczema		
Dermatitis allergic	2	2 0
Erythemas		
Erythema	2	2 0
Pruritus NEC		
Pruritus	7	0
Rashes, eruptions and exanthems NEC		
Rash	10	0
Rash papular		0
Skin and subcutaneous conditions NEC		
Skin mass		0
Subcutaneous emphysema	1	0
Urticarias		
Urticaria	2	2 0
Skin disorders SOC TOTAL	35	il o

Name: Electronic Cigarette Drug Analysis Print

Report Run Date: 17-Apr-2024
Earliest Reaction Date: 01-Jan-2010

Data Lock Date: 16-Apr-2024 18:30:03
MedDRA Version: MedDRA 26.1

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 hypotensive disorders		
Hypotension	1	0
Vascular disorders SOC TOTAL	6	0
TOTAL REACTIONS FOR DRUG	1024	5
TOTAL REPORTS	374	
TOTAL FATAL OUTCOME REPORTS		5