



PMI RESEARCH & DEVELOPMENT

Safety Update Report

Tobacco Heating System / IQOS

Appendix 6 Cumulative and Interval Summary Tabulations of Serious and Non-Serious Adverse Reactions from Post-Marketing data sources

Report Number: PMI_SURV_2016_SUR01

International Birth Date: 04 Nov 2014

Interval Covered: 01 May 2015 to 31 Dec 2015

Products Covered: Tobacco Heating System 2.2 and 2.4 / All variants

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Cumulative and Interval Summary Tabulations of Serious and Non-Serious Adverse Reactions from Post-Marketing data sources

	Spontaneous source					Premarket studies	
	Serious		Non-serious		Total	Serious	
System Organ Class Preferred Term	Interval	Cumulative	Interval	Cumulative	Cumulative	Interval	Cumulative
Cardiac disorders	0	0	0	2	2	0	0
Tachycardia	0	0	0	2	2	0	0
Eye disorders	0	0	0	1	1	0	0
Chromatopsia	0	0	0	1	0	0	0
Gastrointestinal disorders	0	0	32	47	47	0	0
Abdominal pain	0	0	1	1	1	0	0
Abdominal pain upper	0	0	2	2	2	0	0
Diarrhoea	0	0	1	1	1	0	0
Dyspepsia	0	0	2	3	3	0	0
Gastric disorder	0	0	0	1	1	0	0
Gingival disorder	0	0	0	1	1	0	0
Glossitis	0	0	0	1	1	0	0
Glossodynia	0	0	1	2	2	0	0
Lip blister	0	0	1	1	1	0	0
Lip swelling	0	0	1	2	2	0	0

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	Spontaneous source					Premarket studies	
	Serious		Non-serious		Total	Serious	
System Organ Class Preferred Term	Interval	Cumulative	Interval	Cumulative	Cumulative	Interval	Cumulative
Mouth ulceration	0	0	0	1	1	0	0
Nausea	0	0	12	15	15	0	0
Oral discomfort	0	0	2	2	2	0	0
Oral mucosal discolouration	0	0	1	2	2	0	0
Oral pain	0	0	2	2	2	0	0
Paraesthesia oral	0	0	2	2	2	0	0
Salivary hypersecretion	0	0	0	1	1	0	0
Swollen tongue	0	0	0	1	1	0	0
Vomiting	0	0	4	6	6	0	0
General disorders and administrations site conditions	0	0	27	33	33	2	2
Adverse event	0	0	1	1	1	1	1
Asthenia	0	0	1	1	1	0	0
Chest discomfort	0	0	2	2	2	0	0
Chest pain	0	0	1	1	1	0	0
Discomfort	0	0	2	2	2	0	0
Fatigue	0	0	2	2	2	0	0

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	Spontaneous source					Premarket studies	
	Serious		Non-serious		Total	Serious	
System Organ Class Preferred Term	Interval	Cumulative	Interval	Cumulative	Cumulative	Interval	Cumulative
Feeling hot	0	0	1	2	2	0	0
Injury associated with device	0	0	0	0	0	1	1
Malaise	0	0	9	12	12	0	0
Mucosal induration	0	0	1	2	2	0	0
Pain	0	0	2	2	2	0	0
Pyrexia	0	0	1	1	1	0	0
Sensation of foreign body	0	0	2	2	2	0	0
Sluggishness	0	0	1	1	1	0	0
Unevaluable event	0	0	1	2	2	0	0
Infections and infestations	0	0	1	2	2	6	6
Abscess oral	0	0	1	2	2	0	0
Bronchitis	0	0	0	0	0	1	1
Cholecystitis infective	0	0	0	0	0	1	1
Ear infection	0	0	0	0	0	1	1
Osteomyelitis	0	0	0	0	0	1	1
Pneumonia	0	0	0	0	0	1	1

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	Spontaneous source					Premarket studies	
	Serious		Non-serious		Total	Serious	
System Organ Class Preferred Term	Interval	Cumulative	Interval	Cumulative	Cumulative	Interval	Cumulative
Sepsis	0	0	0	0	0	1	1
Injury, poisoning and procedural complications	0	0	9	9	9	12	12
Accident	0	0	0	0	0	1	1
Burn oral cavity	0	0	2	2	2	0	0
Burns second degree	0	0	1	1	1	0	0
Concussion	0	0	0	0	0	1	1
Fall	0	0	0	0	0	1	1
Head injury	0	0	0	0	0	1	1
Joint injury	0	0	0	0	0	1	1
Limb injury	0	0	0	0	0	1	1
Muscle strain	0	0	0	0	0	1	1
Nerve injury	0	0	0	0	0	1	1
Road traffic accident	0	0	0	0	0	1	1
Skeletal injury	0	0	0	0	0	1	1
Skin abrasion	0	0	0	0	0	1	1
Thermal burn	0	0	5	5	5	1	1

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	Serious		Non-serious		Total	Serious	
System Organ Class Preferred Term	Interval	Cumulative	Interval	Cumulative	Cumulative	Interval	Cumulative
Tobacco poisoning	0	0	1	1	1	0	0
Investigations	0	0	1	3	3	0	0
Blood pressure increased	0	0	0	1	1	0	0
Heart rate increased	0	0	1	2	2	0	0
Muskuloskeletal and connective tissue disorder	0	0	0	0	0	2	2
Spinal disorder	0	0	0	0	0	1	1
Spinal pain	0	0	0	0	0	1	1
Nervous system disorders	2	2	22	26	28	0	0
Aphonia	0	0	1	1	1	0	0
Dizziness	0	0	4	6	6	0	0
Dysgeusia	0	0	1	2	2	0	0
Headache	0	0	14	15	15	0	0
Loss of consciousness	1	1	0	0	1	0	0
Somnolence	0	0	1	1	1	0	0
Syncope	1	1	0	0	1	0	0
Tremor	0	0	1	1	1	0	0

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	Spontaneous source					Premarket studies	
	Serious		Non-serious		Total	Serious	
System Organ Class Preferred Term	Interval	Cumulative	Interval	Cumulative	Cumulative	Interval	Cumulative
Psychiatric disorders	0	0	2	3	3	0	0
Agitation	0	0	0	1	1	0	0
Nervousness	0	0	1	1	1	0	0
Panic reaction	0	0	1	1	1	0	0
Respiratory, thoracic and mediastinal disorders	0	0	29	43	43	1	1
Cough	0	0	6	12	12	0	0
Dry throat	0	0	4	5	5	0	0
Dysphonia	0	0	1	1	1	0	0
Dyspnoea	0	0	3	3	3	0	0
Haemoptysis	0	0	1	1	1	0	0
Laryngeal discomfort	0	0	2	3	3	0	0
Oropharyngeal discomfort	0	0	0	1	1	0	0
Oropharyngeal pain	0	0	5	9	9	0	0
Productive cough	0	0	2	3	3	0	0
Throat irritation	0	0	5	5	5	0	0
Tonsillar cyst	0	0	0	0	0	1	1

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	Spontaneous source					Premarket studies	
	Serious		Non-serious		Total	Serious	
System Organ Class Preferred Term	Interval	Cumulative	Interval	Cumulative	Cumulative	Interval	Cumulative
Skin and subcutaneous tissue disorder	0	0	2	3	3	0	0
Blister rupture	0	0	1	1	1	0	0
Pruritus	0	0	0	1	1	0	0
Urticaria	0	0	1	1	1	0	0
GRAND TOTAL	2	2	125	172	174	23	23

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