



PMI RESEARCH & DEVELOPMENT

THS Additional Safety Data Report

Tobacco Heating System / IQOS

Appendix 2 Pre-marketing Cumulative Summary Tabulations THS Regular Products

Report Number: PMI_SURV_2016_SSR03

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CUM CDA All Cases Pre-Marketing All THS Regular

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

Advanced Condition used in this report:

Advanced Condition: All THS Regular Ingredients Report From Study/OS (Created by nicole.miller)

Query Set Selection Criteria:

Report From Study/Other Studies INTERSECT

All THS Regular Ingredients

Advanced Conditions used in this query set:

Advanced Condition: Report From Study/Other Studies (Created by nicole.miller)

Selection Criteria:

(Case Report Type equal to Report From Study AND

Observe Study Type equal to Other Studies)

Advanced Condition: All THS Regular Ingredients (Created by Joshua Cox)

Selection Criteria:

(Ingredient equal to D2 Ron OR

Ingredient equal to D2 Ron (cork tipping paper) OR

Ingredient equal to D1 Fitz OR

Ingredient equal to D2 Albertino OR

Ingredient equal to D2 Fitz OR

Ingredient equal to Ginebra Fitz OR

Ingredient equal to D2 Ron (half white tipping paper) OR

Ingredient equal to Ron OR

Ingredient equal to Scion 1 Fitz OR

Ingredient equal to Scion 1 Walt)

CUM CDA All Cases Pre-Marketing All THS Regular

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Cardiac disorders	Tachycardia	1	0	1
	SubTotal	1	0	1
Ear and labyrinth disorders	Vertigo	1	0	1
	SubTotal	1	0	1
Eye disorders	Eye irritation	1	0	1
	Eyelid disorder	1	0	1
	SubTotal	2	0	2
Gastrointestinal disorders	Abdominal discomfort	7	0	7
	Abdominal distension	1	0	1
	Abdominal pain upper	2	0	2
	Dry mouth	1	0	1
	Dyspepsia	4	0	4
	Dysphagia	2	0	2
	Eructation	2	0	2
	Frequent bowel movements	1	0	1
	Gingival pain	1	0	1
	Glossitis	1	0	1
	Hypoaesthesia oral	1	0	1
	Lip blister	1	0	1
	Nausea	51	0	51
	Odynophagia	1	0	1
	Oesophageal pain	1	0	1
	Oral discomfort	7	0	7
	Oral pain	1	0	1

CUM CDA All Cases Pre-Marketing All THS Regular

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Gastrointestinal disorders	Oral pruritus	1	0	1
	Paraesthesia oral	1	0	1
	Retching	2	0	2
	Salivary hypersecretion	1	0	1
	Stomatitis	2	0	2
	Tongue coated	1	0	1
	Tongue discolouration	1	0	1
	Vomiting	5	0	5
	SubTotal	99	0	99
General disorders and administration site conditions	Chest discomfort	14	0	14
	Chest pain	5	0	5
	Condition aggravated	1	0	1
	Device battery issue	1	0	1
	Device damage	1	0	1
	Device difficult to use	2	0	2
	Device issue	3	0	3
	Device malfunction	3	0	3
	Discomfort	1	0	1
	Feeling abnormal	5	0	5
	Feeling hot	9	0	9
	Hunger	1	0	1

CUM CDA All Cases Pre-Marketing All THS Regular

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
General disorders and administration site conditions	Injury associated with device	0	1	1
	Malaise	13	0	13
	Pre-existing condition improved	1	0	1
	Product odour abnormal	4	0	4
	Product quality issue	14	0	14
	Product taste abnormal	50	0	50
	Pyrexia	2	0	2
	Sensation of foreign body	1	0	1
	Sense of oppression	1	0	1
	SubTotal	132	1	133
Immune system disorders	Hypersensitivity	1	0	1
	SubTotal	1	0	1
Infections and infestations	Bronchitis	1	0	1
	Cholecystitis infective	0	1	1
	Influenza	1	0	1
	Laryngitis	1	0	1
	Nasopharyngitis	1	0	1
	Osteomyelitis	0	1	1

CUM CDA All Cases Pre-Marketing All THS Regular

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		Total
		No	Yes	
Infections and infestations	Pharyngitis streptococcal	1	0	1
	Pneumonia	0	1	1
	Respiratory tract infection	1	0	1
	Sepsis	0	1	1
	Sinusitis	1	0	1
	Tonsillitis	1	0	1
	Tracheitis	1	0	1
	SubTotal	9	4	13
Injury, poisoning and procedural complications	Accident	0	1	1
	Burns second degree	1	0	1
	Concussion	0	1	1
	Fall	0	1	1
	Joint injury	0	1	1
	Limb injury	0	1	1
	Maternal exposure timing unspecified	1	0	1
	Muscle strain	0	1	1
	Nerve injury	0	1	1
	Road traffic accident	0	1	1
	Skeletal injury	0	1	1
	Skin abrasion	0	1	1
	Thermal burn	1	1	2

CUM CDA All Cases Pre-Marketing All THS Regular

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		Total
		No	Yes	
Injury, poisoning and procedural complications	Wrong technique in product usage process	1	0	1
	SubTotal	4	11	15
Investigations	Heart rate increased	1	0	1
	SubTotal	1	0	1
Musculoskeletal and connective tissue disorders	Spinal disorder	0	1	1
	Spinal pain	0	1	1
	SubTotal	0	2	2
Nervous system disorders	Dizziness	13	0	13
	Dysgeusia	27	0	27
	Headache	54	0	54
	Movement disorder	1	0	1
	Somnolence	2	0	2
	SubTotal	97	0	97
Psychiatric disorders	Anxiety	1	0	1
	Aversion	1	0	1
	SubTotal	2	0	2
Respiratory, thoracic and mediastinal disorders	Bronchial irritation	1	0	1
	Bronchial secretion retention	1	0	1

CUM CDA All Cases Pre-Marketing All THS Regular

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		Total
		No	Yes	
Respiratory, thoracic and mediastinal disorders	Choking sensation	1	0	1
	Chronic obstructive pulmonary disease	1	0	1
	Cough	47	0	47
	Cough decreased	1	0	1
	Dry throat	10	0	10
	Dysphonia	1	0	1
	Dyspnoea	1	0	1
	Hiccups	1	0	1
	Laryngeal discomfort	3	0	3
	Nasal discomfort	1	0	1
	Oropharyngeal pain	20	0	20
	Pharyngeal oedema	4	0	4
	Productive cough	2	0	2
	Respiratory tract irritation	3	0	3
	Sputum discoloured	1	0	1
	Sputum retention	1	0	1
	Suffocation feeling	1	0	1
	Throat irritation	32	0	32

CUM CDA All Cases Pre-Marketing All THS Regular

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		Total
		No	Yes	
Respiratory, thoracic and mediastinal disorders	Tracheal inflammation	1	0	1
	SubTotal	134	0	134
Skin and subcutaneous tissue disorders	Cold sweat	1	0	1
	Decubitus ulcer	1	0	1
	SubTotal	2	0	2
Total		485	18	503

CUM Tab All Events From Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

Advanced Condition used in this report:

Advanced Condition: Ingredient D2 Ron/D2 Fitz (Created by nicole.miller)

Query Set Selection Criteria:

Report From Study/Other Studies INTERSECT

Ingredients D2 Ron/D2 Fitz

Advanced Conditions used in this query set:

Advanced Condition: Report From Study/Other Studies (Created by nicole.miller)

Selection Criteria:

(Case Report Type equal to Report From Study AND

Observe Study Type equal to Other Studies)

Advanced Condition: Ingredients D2 Ron/D2 Fitz (Created by nicole.miller)

Selection Criteria:

Ingredient equal to D2 Ron OR

Ingredient equal to D2 Fitz OR

Ingredient equal to D2 Ron (half white tipping paper) OR

Ingredient equal to D2 Ron (cork tipping paper)

CUM Tab All Events From Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Cardiac disorders	Tachycardia	1	0	1
	SubTotal	1	0	1
Eye disorders	Eye irritation	1	0	1
	Eyelid disorder	1	0	1
	SubTotal	2	0	2
Gastrointestinal disorders	Abdominal discomfort	6	0	6
	Abdominal distension	1	0	1
	Abdominal pain upper	1	0	1
	Dysphagia	2	0	2
	Eructation	2	0	2
	Frequent bowel movements	1	0	1
	Glossitis	1	0	1
	Hypoaesthesia oral	1	0	1
	Lip blister	1	0	1
	Nausea	32	0	32
	Odynophagia	1	0	1
	Oesophageal pain	1	0	1
	Oral discomfort	6	0	6
	Oral pain	1	0	1
	Oral pruritus	1	0	1
	Paraesthesia oral	1	0	1
	Retching	1	0	1
	Stomatitis	2	0	2
	Tongue coated	1	0	1
	Vomiting	3	0	3
	SubTotal	66	0	66

CUM Tab All Events From Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
General disorders and administration site conditions	Chest discomfort	10	0	10
	Chest pain	3	0	3
	Condition aggravated	1	0	1
	Device difficult to use	1	0	1
	Device issue	3	0	3
	Device malfunction	2	0	2
	Discomfort	1	0	1
	Feeling abnormal	4	0	4
	Feeling hot	3	0	3
	Hunger	1	0	1
	Malaise	13	0	13
	Pre-existing condition improved	1	0	1
	Product odour abnormal	2	0	2
	Product quality issue	13	0	13
	Product taste abnormal	18	0	18
	Pyrexia	1	0	1
	Sensation of foreign body	1	0	1
	Sense of oppression	1	0	1
	SubTotal	79	0	79

CUM Tab All Events From Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Immune system disorders	Hypersensitivity	1	0	1
	SubTotal	1	0	1
Infections and infestations	Bronchitis	1	0	1
	Cholecystitis infective	0	1	1
	Influenza	1	0	1
	Laryngitis	1	0	1
	Nasopharyngitis	1	0	1
	Osteomyelitis	0	1	1
	Pharyngitis streptococcal	1	0	1
	Pneumonia	0	1	1
	Respiratory tract infection	1	0	1
	Sepsis	0	1	1
	Sinusitis	1	0	1
	Tracheitis	1	0	1
	SubTotal	8	4	12
Injury, poisoning and procedural complications	Accident	0	1	1
	Burns second degree	1	0	1
	Concussion	0	1	1
	Joint injury	0	1	1
	Limb injury	0	1	1

CUM Tab All Events From Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Injury, poisoning and procedural complications	Maternal exposure timing unspecified	1	0	1
	Muscle strain	0	1	1
	Nerve injury	0	1	1
	Road traffic accident	0	1	1
	Skeletal injury	0	1	1
	Skin abrasion	0	1	1
	Thermal burn	1	0	1
	Wrong technique in product usage process	1	0	1
	SubTotal	4	9	13
Investigations	Heart rate increased	1	0	1
	SubTotal	1	0	1
Nervous system disorders	Dizziness	7	0	7
	Dysgeusia	19	0	19
	Headache	44	0	44
	Movement disorder	1	0	1
	Somnolence	2	0	2
	SubTotal	73	0	73
Psychiatric disorders	Anxiety	1	0	1
	Aversion	1	0	1
	SubTotal	2	0	2

CUM Tab All Events From Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		Total
		No	Yes	
Respiratory, thoracic and mediastinal disorders	Bronchial irritation	1	0	1
	Choking sensation	1	0	1
	Chronic obstructive pulmonary disease	1	0	1
	Cough	25	0	25
	Cough decreased	1	0	1
	Dry throat	7	0	7
	Dyspnoea	1	0	1
	Nasal discomfort	1	0	1
	Oropharyngeal pain	15	0	15
	Pharyngeal oedema	1	0	1
	Productive cough	1	0	1
	Respiratory tract irritation	1	0	1
	Sputum discoloured	1	0	1
	Sputum retention	1	0	1
	Suffocation feeling	1	0	1
	Throat irritation	18	0	18
	SubTotal	77	0	77
Skin and subcutaneous tissue disorders	Cold sweat	1	0	1

CUM Tab All Events From Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		Total
		No	Yes	
Skin and subcutaneous tissue disorders	Decubitus ulcer	1	0	1
	SubTotal	2	0	2
Total		316	13	329

CUM CDA All Cases Excluding D2 Ron and D2 Fitz

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

Advanced Condition used in this report:

Advanced Condition: All cases Excluding D2 Ron and D2 Fitz (Created by nicole.miller)

Query Set Selection Criteria:

Report From Study/Other Studies INTERSECT

Regular THS Ingredients Minus D2 Ron/ D2 Fitz

Advanced Conditions used in this query set:

Advanced Condition: Report From Study/Other Studies (Created by nicole.miller)

Selection Criteria:

(Case Report Type equal to Report From Study AND

Observe Study Type equal to Other Studies)

Advanced Condition: Regular THS Ingredients Minus D2 Ron/ D2 Fitz (Created by nicole.miller)

Selection Criteria:

(Ingredient equal to Ron OR

Ingredient equal to D1 Fitz OR

Ingredient equal to D2 Albertino OR

Ingredient equal to Ginebra Fitz OR

Ingredient equal to Scion 1 Fitz OR

Ingredient equal to Scion 1 Walt)

CUM CDA All Cases Excluding D2 Ron and D2 Fitz

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Ear and labyrinth disorders	Vertigo	1	0	1
	SubTotal	1	0	1
Gastrointestinal disorders	Abdominal discomfort	1	0	1
	Abdominal pain upper	1	0	1
	Dry mouth	1	0	1
	Dyspepsia	4	0	4
	Gingival pain	1	0	1
	Nausea	19	0	19
	Oral discomfort	1	0	1
	Retching	1	0	1
	Salivary hypersecretion	1	0	1
	Tongue discolouration	1	0	1
	Vomiting	2	0	2
	SubTotal	33	0	33
General disorders and administration site conditions	Chest discomfort	4	0	4
	Chest pain	2	0	2
	Device battery issue	1	0	1
	Device damage	1	0	1
	Device difficult to use	1	0	1
	Device malfunction	1	0	1

CUM CDA All Cases Excluding D2 Ron and D2 Fitz

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
General disorders and administration site conditions	Feeling abnormal	1	0	1
	Feeling hot	6	0	6
	Injury associated with device	0	1	1
	Product odour abnormal	2	0	2
	Product quality issue	1	0	1
	Product taste abnormal	32	0	32
	Pyrexia	1	0	1
	SubTotal	53	1	54
Infections and infestations	Tonsillitis	1	0	1
	SubTotal	1	0	1
Injury, poisoning and procedural complications	Fall	0	1	1
	Thermal burn	0	1	1
	SubTotal	0	2	2
Musculoskeletal and connective tissue disorders	Spinal disorder	0	1	1
	Spinal pain	0	1	1
	SubTotal	0	2	2
Nervous system disorders	Dizziness	6	0	6

CUM CDA All Cases Excluding D2 Ron and D2 Fitz

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Mar-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		Total
		No	Yes	
Nervous system disorders	Dysgeusia	8	0	8
	Headache	10	0	10
	SubTotal	24	0	24
Respiratory, thoracic and mediastinal disorders	Bronchial secretion retention	1	0	1
	Cough	22	0	22
	Dry throat	3	0	3
	Dysphonia	1	0	1
	Hiccups	1	0	1
	Laryngeal discomfort	3	0	3
	Oropharyngeal pain	5	0	5
	Pharyngeal oedema	3	0	3
	Productive cough	1	0	1
	Respiratory tract irritation	2	0	2
	Throat irritation	14	0	14
	Tracheal inflammation	1	0	1
	SubTotal	57	0	57
Total		169	5	174