



PMI RESEARCH & DEVELOPMENT

THS Additional Safety Data Report

Tobacco Heating System / IQOS

Appendix 3 Pre-marketing Cumulative Summary Tabulations THS Menthol Products

Report Number: PMI_SURV_2016_SSR03

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CUM CDA All Cases Pre-Marketing All THS Menthol

For All Products (Number of Events)

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

Advanced Condition used in this report:

Advanced Condition: Pre-Marketing Studies All THS Menthol (Created by nicole.miller)

Query Set Selection Criteria:

Report From Study/Other Studies INTERSECT

Ingredients All THS Menthol MINUS

Minus Cases PMI000137 & PMI000150

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 All THS Menthol (Created by nicole.miller)

Selection Criteria:

Ingredient equal to Mint Veronica OR

Ingredient equal to Vinny/Ron (half white tipping paper) OR

Ingredient equal to D1 Vinny Low Menthol

Advanced Condition: Minus Cases PMI000137 & PMI000150 (Created by nicole.miller)

Selection Criteria:

Case Number equal to PMI000137 OR

Case Number equal to PMI000150

CUM CDA All Cases Pre-Marketing All THS Menthol

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	2	0	2
	Abdominal pain upper	2	0	2
	Diarrhoea	2	0	2
	Dry mouth	2	0	2
	Dyspepsia	1	0	1
	Gingival pain	1	0	1
	Nausea	11	0	11
	Oral discomfort	2	0	2
	Oral pain	1	0	1
	Retching	1	0	1
	Salivary hypersecretion	1	0	1
	Tongue pruritus	1	0	1
	Vomiting	1	0	1
	SubTotal	28	0	28
General disorders and administration site conditions	Adverse event	0	1	1
	Chest discomfort	2	0	2
	Chest pain	2	0	2
	Device battery issue	1	0	1
	Device damage	1	0	1
	Device defective	1	0	1

CUM CDA All Cases Pre-Marketing All THS Menthol

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	Device difficult to use	5	0	5
	Device issue	2	0	2
	Device use error	1	0	1
	Discomfort	1	0	1
	Energy increased	1	0	1
	Fatigue	1	0	1
	Feeling hot	3	0	3
	Injury associated with device	0	1	1
	Malaise	8	0	8
	Pain	1	0	1
	Product odour abnormal	5	0	5
	Product quality issue	5	0	5
	Product taste abnormal	11	0	11
	Pyrexia	1	0	1
	Unevaluable event	1	0	1
	SubTotal	53	2	55
Infections and infestations	Bronchitis	0	1	1
	Ear infection	0	1	1
	Influenza	1	0	1
	Nasopharyngitis	2	0	2
	Osteomyelitis	0	1	1

CUM CDA All Cases Pre-Marketing All THS Menthol

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
Infections and infestations	Pharyngitis streptococcal	1	0	1
	Respiratory tract infection	1	0	1
	SubTotal	5	3	8
Injury, poisoning and procedural complications	Accident	0	1	1
	Head injury	0	1	1
	Limb injury	0	1	1
	Maternal exposure timing unspecified	1	0	1
	Nerve injury	1	1	2
	Respiratory fume inhalation disorder	1	0	1
	Skeletal injury	0	1	1
	Thermal burn	0	1	1
	Wrong technique in product usage process	1	0	1
	SubTotal	4	6	10
Musculoskeletal and connective tissue disorders	Muscular weakness	1	0	1
	SubTotal	1	0	1
Nervous system disorders	Dizziness	9	0	9
	Dysgeusia	5	0	5
	Head discomfort	1	0	1

CUM CDA All Cases Pre-Marketing All THS Menthol

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
Nervous system disorders	Headache	14	0	14
	Hyperaesthesia	1	0	1
	Loss of consciousness	1	0	1
	Neuralgia	1	0	1
	Somnolence	1	0	1
	SubTotal	33	0	33
Psychiatric disorders	Mental status changes	1	0	1
	SubTotal	1	0	1
Respiratory, thoracic and mediastinal disorders	Cough	19	0	19
	Dry throat	3	0	3
	Dysphonia	1	0	1
	Dyspnoea	1	0	1
	Laryngeal discomfort	2	0	2
	Oropharyngeal pain	9	0	9
	Pharyngeal disorder	1	0	1
	Pharyngeal oedema	1	0	1
	Productive cough	2	0	2
	Sputum discoloured	1	0	1

CUM CDA All Cases Pre-Marketing All THS Menthol

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	Throat irritation	10	0	10
	Tonsillar cyst	0	1	1
	SubTotal	50	1	51
Surgical and medical procedures	Hospitalisation	0	1	1
	SubTotal	0	1	1
Vascular disorders	Hypotension	1	0	1
	SubTotal	1	0	1
Total		177	13	190

CUM CDA Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron

For All Products (Number of Events)

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

Advanced Condition used in this report:

Advanced Condition: THS Menthol D1 Vinny Low Menthol and Vinny / Ron (Created by nicole.miller)

Query Set Selection Criteria:

Report From Study/Other Studies INTERSECT

Ingredient Vinny/Ron and D1 Vinny Low Menthol MINUS

Minus Cases PMI000137 & PMI000150

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: Ingredient Vinny/Ron and D1 Vinny Low Menthol (Created by nicole.miller)

Selection Criteria:

Ingredient equal to Vinny/Ron (half white tipping paper) OR

Ingredient equal to D1 Vinny Low Menthol

Advanced Condition: Minus Cases PMI000137 & PMI000150 (Created by nicole.miller)

Selection Criteria:

Case Number equal to PMI000137 OR

Case Number equal to PMI000150

CUM CDA Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron

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	2	0	2
	Abdominal pain upper	2	0	2
	Diarrhoea	2	0	2
	Dry mouth	2	0	2
	Dyspepsia	1	0	1
	Gingival pain	1	0	1
	Nausea	6	0	6
	Oral discomfort	2	0	2
	Oral pain	1	0	1
	Retching	1	0	1
	Salivary hypersecretion	1	0	1
	Tongue pruritus	1	0	1
	Vomiting	1	0	1
	SubTotal	23	0	23
General disorders and administration site conditions	Adverse event	0	1	1
	Chest discomfort	1	0	1
	Chest pain	2	0	2
	Device battery issue	1	0	1
	Device damage	1	0	1
	Device defective	1	0	1

CUM CDA Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron

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	
General disorders and administration site conditions	Device difficult to use	5	0	5
	Device issue	2	0	2
	Device use error	1	0	1
	Discomfort	1	0	1
	Energy increased	1	0	1
	Fatigue	1	0	1
	Feeling hot	3	0	3
	Injury associated with device	0	1	1
	Malaise	8	0	8
	Pain	1	0	1
	Product odour abnormal	4	0	4
	Product quality issue	5	0	5
	Product taste abnormal	8	0	8
	Unevaluable event	1	0	1
	SubTotal	47	2	49
Infections and infestations	Bronchitis	0	1	1
	Ear infection	0	1	1
	Nasopharyngitis	2	0	2
	Osteomyelitis	0	1	1
	Pharyngitis streptococcal	1	0	1

CUM CDA Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron

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	Respiratory tract infection	1	0	1
	SubTotal	4	3	7
Injury, poisoning and procedural complications	Accident	0	1	1
	Head injury	0	1	1
	Limb injury	0	1	1
	Maternal exposure timing unspecified	1	0	1
	Nerve injury	1	1	2
	Respiratory fume inhalation disorder	1	0	1
	Skeletal injury	0	1	1
	Thermal burn	0	1	1
	Wrong technique in product usage process	1	0	1
	SubTotal	4	6	10
Musculoskeletal and connective tissue disorders	Muscular weakness	1	0	1
	SubTotal	1	0	1
Nervous system disorders	Dizziness	7	0	7
	Dysgeusia	5	0	5
	Head discomfort	1	0	1
	Headache	12	0	12
	Hyperaesthesia	1	0	1

CUM CDA Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron

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	Loss of consciousness	1	0	1
	Neuralgia	1	0	1
	Somnolence	1	0	1
	SubTotal	29	0	29
Psychiatric disorders	Mental status changes	1	0	1
	SubTotal	1	0	1
Respiratory, thoracic and mediastinal disorders	Cough	16	0	16
	Dry throat	3	0	3
	Dysphonia	1	0	1
	Dyspnoea	1	0	1
	Laryngeal discomfort	2	0	2
	Oropharyngeal pain	9	0	9
	Pharyngeal disorder	1	0	1
	Pharyngeal oedema	1	0	1
	Productive cough	2	0	2
	Sputum discoloured	1	0	1
	Throat irritation	9	0	9
	Tonsillar cyst	0	1	1
	SubTotal	46	1	47

CUM CDA Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron

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
Surgical and medical procedures	Hospitalisation	0	1	1
	SubTotal	0	1	1
Vascular disorders	Hypotension	1	0	1
	SubTotal	1	0	1
Total		157	13	170

CUM CDA THS Menthol excluding D1 Vinny Low Menthol and Vinny Ron

For All Products (Number of Events)

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

Advanced Condition used in this report:

Advanced Condition: THS Menth Minus D1 Vinny Low Menth/Vin Ron (Created by nicole.miller)

Query Set Selection Criteria:

Report From Study/Other Studies INTERSECT

Ingredient Mint Veronica

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: Ingredient Mint Veronica (Created by nicole.miller)

Selection Criteria:

Ingredient equal to Mint Veronica

CUM CDA THS Menthol excluding D1 Vinny Low Menthol and Vinny Ron

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	Total
Gastrointestinal disorders	Nausea	5	5
	SubTotal	5	5
General disorders and administration site conditions	Chest discomfort	1	1
	Product odour abnormal	1	1
	Product taste abnormal	3	3
	Pyrexia	1	1
	SubTotal	6	6
Infections and infestations	Influenza	1	1
	SubTotal	1	1
Nervous system disorders	Dizziness	2	2
	Headache	2	2
	SubTotal	4	4
Respiratory, thoracic and mediastinal disorders	Cough	3	3
	Throat irritation	1	1
	SubTotal	4	4
Total		20	20