16.2.7 Adverse Events Listings

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1001	Pre product use	No	Nervous system disorders >Headache >>OCCIPITAL HEADACHE		25JUL2018 18:00/ 25JUL2018 19:30	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
	VLN non-mentholated	Yes	Nervous system disorders >Headache >>OCCIPITAL HEADACHE	42:18:00	06SEP2018 18:00/ 06SEP2018 20:30	Cont.	Moderate	No	Resolved	Not Related	Dose Not Changed
1002	Pre product use	No	Nervous system disorders >Headache >>GENERALIZED HEADACHE		25JUL2018 17:00/ 26JUL2018 3:30	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		No	Gastrointestinal disorders >Dyspepsia >>DYSPEPSIA		25JUL2018 20:30/ 26JUL2018 3:30	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1003	VLN mentholated	Yes	Respiratory, thoracic and mediastinal disorders >Oropharyngeal pain >>SORE THROAT	14:23:30	09AUG2018 23:30/ 10AUG2018 6:30	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		Yes	Musculoskeletal and connective tissue disorders >Back pain >>LOWER BACK PAIN	42:07:15	06SEP2018 7:15/ 07SEP2018 9:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		Yes	Skin and subcutaneous tissue disorders >Pruritus >>PRURITUS TO BACK	42:20:10	06SEP2018 20:10/ 07SEP2018 2:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1007	VLN non-mentholated	Yes	General disorders and administration site conditions >Vessel puncture site pain >>TENDERNESS AT VEINIPUNCTURE SITE LEFT ARM	15:08:40	10AUG2018 8:40/ 10AUG2018 15:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
1008	Pre product use	No	Nervous system disorders >Headache >>FRONTAL HEADACE		25JUL2018 17:00/ 25JUL2018 19:15	Cont.	Mild	No	Resolved	Unlikely	Dose Not Changed
	VLN mentholated	Yes	Gastrointestinal disorders >Toothache >>PAIN TO RIGHT UPPER MOLAR	42:14:30	06SEP2018 14:30/ 07SEP2018 3:37	Inter	Mild	No	Resolved	Not Related	Dose Not Changed
1010	UB mentholated	Yes	Nervous system disorders >Headache >>FRONTAL HEADACHE	14:09:00	09AUG2018 9:00/ 10AUG2018 9:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1011	Pre product use	No	Nervous system disorders >Headache >>OCCIPITAL HEADACHE		24JUL2018 18:45/ 25JUL2018 22:30	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
	UB non-mentholated	Yes	Nervous system disorders >Headache >>BILATERAL TEMPORAL HEADACHE	13:20:25	08AUG2018 20:25/ 09AUG2018 7:20	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		Yes	Gastrointestinal disorders >Nausea >>NAUSEA	13:23:38	08AUG2018 23:38/ 08AUG2018 23:42	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		Yes	Gastrointestinal disorders >Vomiting >>VOMIT X1	13:23:40	08AUG2018 23:40/ 08AUG2018 23:41	SE	Mild	No	Resolved	Not Related	Dose Not Changed
1013	VLN non-mentholated	Yes	Nervous system disorders >Dizziness >>LIGHTHEADEDNESS	00:08:17	02AUG2018 8:17/ 02AUG2018 8:24	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1014	VLN mentholated	Yes	Psychiatric disorders >Irritability >>IRRITABLE	39:19:00	10SEP2018 19:00/ 12SEP2018 22:00	Inter	Mild	No	Resolved	Possible	Dose Not Changed
1015	Pre product use	No	General disorders and administration site conditions >Vessel puncture site pain >>TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE		01AUG2018 13:00/ 02AUG2018 7:15	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
	VLN mentholated	Yes	General disorders and administration site conditions >Vessel puncture site pain >>TENDERNESS AT LEFT ANTECUBITAL VENIPUNCTURE SITE	00:08:20	02AUG2018 8:20/ 04AUG2018 12:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1015	VLN mentholated	Yes	General disorders and administration site conditions >Vessel puncture site pain >>TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE	00:08:20	02AUG2018 8:20/ 04AUG2018 12:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		Yes	Psychiatric disorders >Irritability >>INCREASED IRRITABILITY	01:13:00	03AUG2018 13:00/ 16AUG2018 7:00	Cont.	Mild	No	Resolved	Possible	Dose Not Changed
		Yes	Nervous system disorders >Headache >>GENERALIZED HEADACHE	14:12:00	16AUG2018 12:00/ 17AUG2018 3:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		Yes	Nervous system disorders >Dizziness >>DIZZINESS	15:09:00	17AUG2018 9:00/ 17AUG2018 10:10	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
1016			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1017	UB mentholated	Yes	Psychiatric disorders >Stress >>INCREASED STRESS	10:17:30	12AUG2018 17:30/ 19AUG2018 9:30	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
1018	Pre product use	No	Nervous system disorders >Headache >>OCCIPITAL HEADACHE		01AUG2018 17:30/ 02AUG2018 7:13	Cont.	Mild	No	Resolved	Unlikely	Dose Not Changed
	VLN mentholated	Yes	Gastrointestinal disorders >Constipation >>CONSTIPATION		UNK	SE	Mild	No	UNKNOWN	Possible	Dose Not Changed
		Yes	Gastrointestinal disorders >Nausea >>NAUSEA		UNK	SE	Mild	No	UNKNOWN	Possible	Dose Not Changed
		Yes	General disorders and administration site conditions >Pain >>PAIN		UNK	SE	Mild	No	UNKNOWN	Possible	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1018	VLN mentholated	Yes	Psychiatric disorders >Nightmare >>NIGHTMARES	02:01:30	04AUG2018 1:30/ 15AUG2018 7:45	Inter	Mild	No	Resolved	Possible	Dose Not Changed
		Yes	Psychiatric disorders >Anxiety >>ANXIETY	06:18:30	08AUG2018 18:30/ 08AUG2018 19:00	Cont.	Mild	No	Resolved	Possible	Dose Not Changed
		Yes	General disorders and administration site conditions >Chest discomfort >>HEAVINESS TO CHEST	06:18:30	08AUG2018 18:30/ 08AUG2018 19:00	Cont.	Mild	No	Resolved	Possible	Dose Not Changed
		Yes	Psychiatric disorders >Anxiety >>ANXIETY	12:19:30	14AUG2018 19:30/ 14AUG2018 20:00	Cont.	Mild	No	Resolved	Possible	Drug Withdrawn
		Yes	Psychiatric disorders >Depressed mood >>FEELING SAD	12:19:30	14AUG2018 19:30/ 14AUG2018 20:00	Cont.	Mild	No	Resolved	Possible	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1018	VLN mentholated	Yes	Nervous system disorders >Tremor >>GENERALIZED BODY SHAKES	12:19:30	14AUG2018 19:30/ 14AUG2018 20:00	Inter	Mild	No	Resolved	Possible	Dose Not Changed
		Yes	General disorders and administration site conditions >Chest discomfort >>HEAVINESS TO CHEST	12:19:30	14AUG2018 19:30/ 14AUG2018 22:30	Inter	Mild	No	Resolved	Possible	Dose Not Changed
		Yes	Nervous system disorders >Headache >>GENERALIZED HEADACHE	12:21:30	14AUG2018 21:30	Cont.	Mild	No	UNKNOWN	Possible	Dose Not Changed
1019	VLN non-mentholated	Yes	Nervous system disorders >Presyncope >>VASOVAGAL REACTION	00:08:17	02AUG2018 8:17/ 02AUG2018 8:26	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1019	VLN non-mentholated	Yes	Psychiatric disorders >Irritability >>INCREASED IRRITABILITY	00:20:00	02AUG2018 20:00/ 16AUG2018 7:00	Cont.	Mild	No	Resolved	Possible	Dose Not Changed
1020	VLN non-mentholated	Yes	Gastrointestinal disorders >Nausea >>NAUSEA	18:12:00	20AUG2018 12:00/ 30AUG2018 12:00	Inter	Mild	No	Resolved	Likely	Dose Not Changed
1021	UB non-mentholated	Yes	Nervous system disorders >Headache >>PARIETAL HEADACHE	14:08:00	16AUG2018 8:00/ 16AUG2018 14:00	Cont.	Moderate	No	Resolved	Not Related	Dose Not Changed
1023	VLN non-mentholated	Yes	Nervous system disorders >Headache >>TEMPORAL HEADACHE	14:14:30	16AUG2018 14:30/ 17AUG2018 15:00	Cont.	Moderate	No	Resolved	Possible	Dose Not Changed
		Yes	Nervous system disorders >Headache >>OCCIPITAL HEADACHE	17:18:30	19AUG2018 18:30/ 02SEP2018 13:30	Inter	Mild	No	Resolved	Possible	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1023	VLN non-mentholated	Yes	General disorders and administration site conditions >Vessel puncture site pain >>TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE	43:09:50	14SEP2018 9:50/ 15SEP2018 14:00	Inter	Mild	No	Resolved	Not Related	Dose Not Changed
		Yes	Injury, poisoning and procedural complications >Subarachnoid haemorrhage >>SUBARACHNOID HEMORRHAGE	44:00:00	15SEP2018 / 02OCT2018	Cont.	Severe	Yes	Resolved	Not Related	Dose Not Changed
1029			None								
1032	VLN mentholated	Yes	Metabolism and nutrition disorders >Increased appetite >>INCREASED APPETITE	02:20:00	31AUG2018 20:00/ 01OCT2018 12:00	Inter	Mild	No	Resolved	Possible	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1032	VLN mentholated	Yes	Psychiatric disorders >Insomnia >>INSOMNIA	03:02:00	01SEP2018 2:00/ 26SEP2018 22:00	Cont.	Mild	No	Resolved	Possible	Dose Not Changed
		Yes	General disorders and administration site conditions >Fatigue >>FATIGUE	03:06:30	01SEP2018 6:30/ 27SEP2018 6:15	Cont.	Mild	No	Resolved	Possible	Dose Not Changed
		Yes	Nervous system disorders >Lethargy >>LETHARGY	03:06:30	01SEP2018 6:30/ 27SEP2018 6:15	Cont.	Mild	No	Resolved	Possible	Dose Not Changed
		Yes	Psychiatric disorders >Irritability >>IRRITABILITY	03:18:00	01SEP2018 18:00/ 12OCT2018 12:00	Cont.	Mild	No	Resolved	Possible	Dose Not Changed
		Yes	Nervous system disorders >Headache >>GENERALIZED HEADACHE	14:16:00	12SEP2018 16:00/ 12SEP2018 21:00	Cont.	Moderate	No	Resolved	Unlikely	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1032	VLN mentholated	Yes	General disorders and administration site conditions >Vessel puncture site pain >>PAIN TO VENIPUNCTURE SITE RIGHT ARM	15:09:01	13SEP2018 9:01/ 13SEP2018 15:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		Yes	Nervous system disorders >Headache >>FRONTAL HEADACHE	42:14:45	10OCT2018 14:45/ 10OCT2018 16:30	Cont.	Mild	No	Resolved	Unlikely	Dose Not Changed
1034			None								
1035			None								
1036	Pre product use	No	Nervous system disorders >Headache >>FRONTAL HEADACHE		28AUG2018 6:30/ 29AUG2018 17:00	Inter	Mild	No	Resolved	Not Related	Dose Not Changed
1037			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1038	Pre product use	No	Eye disorders >Ocular hyperaemia >>RIGHT EYE ERYTHEMATOUS		28AUG2018 6:15/ 28AUG2018 9:00	Cont.	Mild	No	Resolved	Not Related	NAP
		No	Eye disorders >Lacrimation increased >>RIGHT EYE EXCESS WATERING		28AUG2018 6:15/ 28AUG2018 9:00	Cont.	Mild	No	Resolved	Not Related	NAP
		No	Eye disorders >Eye pruritus >>RIGHT EYE FEELS SCRATCHY		28AUG2018 6:15/ 28AUG2018 9:00	Cont.	Mild	No	Resolved	Not Related	NAP
1042			None								
1045			None								
1046			None								
1050	VLN non-mentholated	Yes	Psychiatric disorders >Insomnia >>INSOMNIA	04:08:00	02SEP2018 8:00/ 12OCT2018 8:00	Cont.	Mild	No	Resolved	Possible	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1050	VLN non-mentholated	Yes	Psychiatric disorders >Irritability >>IRRITABILITY	06:20:00	04SEP2018 20:00/ 12OCT2018 11:00	Inter	Mild	No	Resolved	Possible	Dose Not Changed
1051			None								
1052	VLN mentholated	Yes	Skin and subcutaneous tissue disorders >Pruritus >>PRURITUS TO BILATERAL ARMS	41:17:00	09OCT2018 17:00/ 10OCT2018 23:00	Inter	Mild	No	Resolved	Unlikely	Dose Not Changed
		Yes	Skin and subcutaneous tissue disorders >Pruritus >>PRURITUS TO BILATERAL LEGS	41:17:00	09OCT2018 17:00/ 10OCT2018 23:00	Inter	Mild	No	Resolved	Unlikely	Dose Not Changed
1053			None								
1054			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1055	VLN mentholated	Yes	Nervous system disorders >Headache >>FRONTAL HEADACHE	14:12:30	12SEP2018 12:30/ 12SEP2018 19:30	Cont.	Moderate	No	Resolved	Unlikely	Dose Not Changed
		Yes	Psychiatric disorders >Irritability >>IRRITABILITY	33:09:00	01OCT2018 9:00/ 11OCT2018 9:30	Cont.	Mild	No	Resolved	Possible	Dose Not Changed
1056			None								
1058	VLN non-mentholated	Yes	Infections and infestations >Tooth infection >>TOOTH INFECTION	12:10:30	10SEP2018 10:30/ 15SEP2018 8:00	Cont.	Moderate	No	Resolved	Not Related	Dose Not Changed
1059	Pre product use	No	Nervous system disorders >Headache >>FRONTAL HEADACHE		11SEP2018 11:40/ 11SEP2018 21:30	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1059	Pre product use	No	Gastrointestinal disorders >Vomiting >>VOMIT X3		11SEP2018 12:40/ 11SEP2018 12:56	Inter	Moderate	No	Resolved	Not Related	Dose Not Changed
	UB non-mentholated	Yes	Nervous system disorders >Headache >>FRONTAL HEADACHE	13:22:00	25SEP2018 22:00/ 26SEP2018 22:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		Yes	Gastrointestinal disorders >Dyspepsia >>DYSPEPSIA	14:13:30	26SEP2018 13:30/ 26SEP2018 14:49	Inter	Mild	No	Resolved	Not Related	Dose Not Changed
		Yes	Gastrointestinal disorders >Vomiting >>VOMIT	14:14:47	26SEP2018 14:47/ 26SEP2018 14:48	SE	Mild	No	Resolved	Not Related	Dose Not Changed
1060			None								
1063	Pre product use	No	Nervous system disorders >Headache >>SLIGHT HEADACHE		11SEP2018 13:15/ 11SEP2018 20:30	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1064	Pre product use	No	Gastrointestinal disorders >Abdominal discomfort >>BURNING SENSATION TO LEFT UPPER ABDOMEN		11SEP2018 6:23/ 25SEP2018 15:45	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		No	Injury, poisoning and procedural complications >Contusion >>CONTUSION TO LEFT UPPER ABDOMEN		11SEP2018 6:23/ 25SEP2018 15:45	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
1066	Pre product use	No	Nervous system disorders >Headache >>FRONTAL HEADACHE		11SEP2018 11:00/ 12SEP2018 13:30	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
1069			None								
1070			None								
1071			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1072			None								
1074			None								
1075	Pre product use	No	Nervous system disorders >Headache >>FRONTAL HEADACHE		11SEP2018 12:41/ 12SEP2018 7:00	Cont.	Mild	No	Resolved	Unlikely	Dose Not Changed
1077	VLN non-mentholated	Yes	Nervous system disorders >Headache >>GENERALIZED HEADACHE	04:08:00	16SEP2018 8:00/ 16SEP2018 10:00	Cont.	Mild	No	Resolved	Unlikely	Dose Not Changed
1078	VLN non-mentholated	Yes	Nervous system disorders >Headache >>FRONTAL HEADACHE	42:12:00	24OCT2018 12:00/ 24OCT2018 22:00	Cont.	Mild	No	Resolved	Unlikely	Dose Not Changed
1079	VLN mentholated	Yes	General disorders and administration site conditions >Fatigue >>FATIGUE	42:06:00	24OCT2018 6:00/ 24OCT2018 16:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1079	VLN mentholated	Yes	Musculoskeletal and connective tissue disorders >Neck pain >>LEFT SIDE NECK PAIN	42:06:00	24OCT2018 6:00/ 24OCT2018 16:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
1082			None								
1083			None								
1084			None								
1086	Pre product use	No	Nervous system disorders >Headache >>FRONTAL HEADACHE		18SEP2018 16:00/ 18SEP2018 16:55	Cont.	Mild	No	Resolved	Unlikely	Dose Not Changed
	VLN non-mentholated	Yes	Nervous system disorders >Headache >>GENERALIZED HEADACHE	05:18:00	24SEP2018 18:00/ 25SEP2018 7:30	Cont.	Mild	No	Resolved	Possible	Dose Not Changed
1088			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1089			None								
1092			None								
1094			None								
1095	Pre product use	No	Skin and subcutaneous tissue disorders >Pruritus >>PRURITUS TO LEFT FOREARM		18SEP2018 4:30/ 18SEP2018 12:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		No	Skin and subcutaneous tissue disorders >Erythema >>ERYTHEMA TO LEFT FOREARM		18SEP2018 7:00/ 19SEP2018 6:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		No	Skin and subcutaneous tissue disorders >Pruritus >>PRURITUS TO PALM OF BILATERAL HANDS		18SEP2018 8:30/ 18SEP2018 12:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1095	Pre product use	No	Skin and subcutaneous tissue disorders >Pruritus >>PRURITUS TO TRUNK		18SEP2018 8:30/ 18SEP2018 12:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		No	Skin and subcutaneous tissue disorders >Palmar erythema >>ERYTHEMA TO PALM OF BILATERAL HANDS		18SEP2018 8:30/ 19SEP2018 6:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		No	Eye disorders >Erythema of eyelid >>ERYTHEMA TO LEFT EYE LID		18SEP2018 9:52/ 19SEP2018 12:30	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
1096			None								
1097	Pre product use	No	Nervous system disorders >Headache >>GENERALIZED HEADACHE		16SEP2018 21:30/ 22SEP2018 8:45	Inter	Mild	No	Resolved	Possible	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1097	Pre product use	No	Gastrointestinal disorders >Dyspepsia >>DYSPEPSIA		18SEP2018 21:30/ 22SEP2018 8:45	Inter	Mild	No	Resolved	Possible	Dose Not Changed
1098	VLN non-mentholated	Yes	Gastrointestinal disorders >Diarrhoea >>LOOSE STOOLS X6	43:07:00	17NOV2018 7:00/ 17NOV2018 15:00	Inter	Mild	No	Resolved	Unlikely	Dose Not Changed
1099			None								
1100			None								
1101	VLN non-mentholated	Yes	Nervous system disorders >Headache >>GENERALIZED HEADACHE	45:12:00	19NOV2018 12:00/ 21NOV2018 8:00	Cont.	Mild	No	Resolved	Possible	Dose Not Changed
1103			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1105	VLN non-mentholated	Yes	Nervous system disorders >Headache >>FRONTAL HEADACHE	02:10:00	07OCT2018 10:00/ 07OCT2018 11:00	Cont.	Mild	No	Resolved	Unlikely	Dose Not Changed
1106			None								
1107			None								
1108	UB non-mentholated	Yes	Injury, poisoning and procedural complications >Laceration >>CUT TO LEFT RING FINGER	12:09:30	17OCT2018 9:30/ 23OCT2018 8:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
1109	UB non-mentholated	Yes	Musculoskeletal and connective tissue disorders >Neck pain >>NECK PAIN	39:15:00	13NOV2018 15:00/ 13NOV2018 19:30	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
1112			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
1114	UB non-mentholated	Yes	Nervous system disorders >Headache >>FRONTAL HEADACHE	13:23:00	18OCT2018 23:00/ 19OCT2018 7:20	Cont.	Mild	No	Resolved	Unlikely	Dose Not Changed
1115			None								
2002			None								
2003			None								
2007			None								
2008			None								
2009			None								
2010			None								
2011			None								
2014			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
2015	Pre product use	No	Vascular disorders >Presyncope >>VASOVAGAL RESPONSE TO RAPID CIGARETTE INHALATION(NON SYNCOPAL)		17JUL2018 13:18/ 17JUL2018 13:36	SE	Moderate	No	Resolved	Not Related	NAP
2016			None								
2017			None								
2018	UB mentholated	Yes	Nervous system disorders >Headache >>HEADACHE	27:08:00	14AUG2018 8:00/ 14AUG2018 12:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
2020	VLN mentholated	Yes	Gastrointestinal disorders >Diarrhoea >>DIARRHEA	42:13:00	29AUG2018 13:00/ 29AUG2018 14:00	Inter	Mild	No	Resolved	Not Related	Dose Not Changed
2021			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
2023	VLN mentholated	Yes	Injury, poisoning and procedural complications >Arthropod bite >>FLEA BITES	36:22:00	23AUG2018 22:00/ 31AUG2018 10:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
2024			None								
2025			None								
2028	VLN non-mentholated	Yes	Nervous system disorders >Headache >>HEADACHE	00:18:00	18JUL2018 18:00/ 19JUL2018 8:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
		Yes	Psychiatric disorders >Irritability >>IRRITABILITY	01:08:05	19JUL2018 8:05/ 04AUG2018 5:00	Inter	Mild	No	Resolved	Not Related	Dose Not Changed
2029			None								
2039			None								
2050			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
2052	VLN mentholated	Yes	Respiratory, thoracic and mediastinal disorders >Throat irritation >>PHARYNGEAL IRRITATION	00:10:00	09AUG2018 10:00/ 29AUG2018 7:00	Cont.	Mild	No	Resolved	Possible	Dose Not Changed
2057			None								
2058			None								
2059	UB mentholated	Yes	Infections and infestations >Nasal abscess >>PARANASAL ABSCESS	04:10:00	13AUG2018 10:00/ 24AUG2018 10:00	Cont.	Moderate	No	Resolved	Not Related	Dose Not Changed
		Yes	Nervous system disorders >Headache >>HEADACHE	40:18:00	18SEP2018 18:00/ 20SEP2018 19:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
2060			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
2064			None								
2066	VLN mentholated	Yes	Nervous system disorders >Headache >>HEADACHE	37:15:00	15SEP2018 15:00/ 16SEP2018 11:30	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
2067			None								
2075			None								
2076			None								
2086	VLN non-mentholated	Yes	Infections and infestations >Upper respiratory tract infection >>UPPER RESPIRATORY TRACT INFECTION	25:17:00	27SEP2018 17:00/ 30SEP2018 8:00	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
2088			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
2092	Pre product use	No	Nervous system disorders >Migraine >>MIGRAINE HEADACHE		01SEP2018 11:45/ 01SEP2018 16:37	Cont.	Moderate	No	Resolved	Not Related	Dose Not Changed
2099			None								
2100			None								
2108			None								
2110			None								
2113	VLN mentholated	Yes	Gastrointestinal disorders >Oral discomfort >>BURNING SENSATION ROOF OF MOUTH	00:13:03	08SEP2018 13:03	Inter	Mild	No	Resolved	Possible	Dose Not Changed
		Yes	Nervous system disorders >Headache >>HEADACHE	03:06:00	11SEP2018 6:00	Cont.	Mild	No	UNKNOWN	Possible	Dose Not Changed
2115			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
2119			None								
2120			None								
2122			None								
2125	UB mentholated	Yes	Injury, poisoning and procedural complications >Meniscus injury >>R KNEE MENISCUS INJURY	07:17:30	15SEP2018 17:30	Cont.	Moderate	No	UNCH	Not Related	Dose Not Changed
2126			None								
2136			None								
2140	UB non-mentholated	Yes	Infections and infestations >Upper respiratory tract infection >>UPPER RESPIRATORY TRACT INFECTION	23:10:30	18OCT2018 10:30/ 25OCT2018 8:30	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
2142			None								
2143			None								
2158	UB non-mentholated	Yes	Nervous system disorders >Headache >>HEADACHE	13:19:50	03NOV2018 19:50/ 04NOV2018 8:15	Cont.	Mild	No	Resolved	Not Related	Dose Not Changed
2159			None								
2164			None								
2168			None								
2170			None								
2175			None								
2189			None								
2211			None								
2212			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
2213			None								
2215			None								
2220			None								
2235			None								
2244	Pre product use	No	Gastrointestinal disorders >Gastrooesophageal reflux disease >>GASTROESOPHAGEAL REFLUX		02NOV2018 21:15/ 02NOV2018 22:00	SE	Mild	No	Resolved	Not Related	Dose Not Changed
2247	VLN mentholated	Yes	Injury, poisoning and procedural complications >Arthropod bite >>INSECT BITES ON BACK AND ARMS	13:11:15	21DEC2018 11:15/ 24DEC2018	Cont.	Moderate	No	Resolved	Not Related	Dose Not Changed
2251			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10

Appendix 16.2.7.1 Adverse Events (Safety Population)

Subject Number	Study Product	UE?^	System Organ Class >Preferred Term* >>Adverse Event	Time From start of Product Use (DD:HH:MM)	Onset Date Time/ Resolved Date Time	Freq#	Severity	Serious	Outcome	Relationship to Study Product	Action
2257	UB non-mentholated	Yes	Neoplasms benign, malignant and unspecified (incl cysts and polyps) >Skin papilloma >>WORSENING PAIN PLANTAR WART	07:18:30	15DEC2018 18:30/ 28JAN2019 4:45	Cont.	Moderate	No	Resolved	Not Related	Dose Not Changed
2259			None								
2269			None								
2272			None								

Note: ^ = Abbreviation for study product use-emergent (UE), UE is assigned to last product used prior to AE start.
* = Adverse events are classified according to the MedDRA Version 21.0, #Freq represents Frequency: SE = Single Episode
Inter = Intermittent, Cont. = Continuous, NAP = Not Applicable, UNK = Unknown, UNCH = Unchanged
VLN non-mentholated = Non-mentholated VLN cigarettes
VLN mentholated = Mentholated VLN cigarettes
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-AE.SAS 18JUN2019 11:10