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14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
PR Interval (msec)	V5 (OLE Week 2)	n	6
		Mean (SD)	-12.8 (15.7)
		Median	-12.5
		Q1 ; Q3	-22.0 ; -4.0
		Min ; Max	-36 ; 10
	V6 (OLE Month 1)	n	5
		Mean (SD)	-14.0 (16.2)
		Median	-8.0
		Q1 ; Q3	-26.0 ; 0.0
		Min ; Max	-36 ; 0
	V7 (OLE Month 2)	n	3
		Mean (SD)	-9.3 (20.0)
		Median	-8.0
		Q1 ; Q3	-30.0 ; 10.0
		Min ; Max	-30 ; 10
	V8 (OLE Month 3)	n	3
		Mean (SD)	-7.3 (12.1)
		Median	-6.0
		Q1 ; Q3	-20.0 ; 4.0
		Min ; Max	-20 ; 4

Source: Listing 14.2

Baseline is defined as the last available measurements obtained during the screening period,
prior to first IMP dose administration during DB period.

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14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
PR Interval (msec)	V11 (OLE Month 12)	n	2
		Mean (SD)	-15.0 (7.1)
		Median	-15.0
		Q1 ; Q3	-20.0 ; -10.0
		Min ; Max	-20 ; -10
	V12 (End of Taper after OLE period)	n	1
		Mean (SD)	22.0
		Median	22.0
		Q1 ; Q3	22.0 ; 22.0
		Min ; Max	22 ; 22
QRS duration (msec)	V5 (OLE Week 2)	n	6
		Mean (SD)	-2.3 (7.9)
		Median	-3.0
		Q1 ; Q3	-6.0 ; 4.0
		Min ; Max	-14 ; 8
	V6 (OLE Month 1)	n	6
		Mean (SD)	-5.7 (6.5)
		Median	-6.0
		Q1 ; Q3	-8.0 ; -6.0
		Min ; Max	-14 ; 6

Source: Listing 14.2

Baseline is defined as the last available measurements obtained during the screening period,
prior to first IMP dose administration during DB period.

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14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
QRS duration (msec)	V7 (OLE Month 2)	n	3
		Mean (SD)	4.7 (6.4)
		Median	2.0
		Q1 ; Q3	0.0 ; 12.0
		Min ; Max	0 ; 12
	V8 (OLE Month 3)	n	3
		Mean (SD)	0.0 (6.0)
		Median	0.0
		Q1 ; Q3	-6.0 ; 6.0
		Min ; Max	-6 ; 6
	V11 (OLE Month 12)	n	2
		Mean (SD)	-7.0 (1.4)
		Median	-7.0
		Q1 ; Q3	-8.0 ; -6.0
		Min ; Max	-8 ; -6
	V12 (End of Taper after OLE period)	n	1
		Mean (SD)	-8.0
		Median	-8.0
		Q1 ; Q3	-8.0 ; -8.0
		Min ; Max	-8 ; -8

Source: Listing 14.2

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prior to first IMP dose administration during DB period.

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14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
QT Interval (msec)	V5 (OLE Week 2)	n	6
		Mean (SD)	-12.3 (13.9)
		Median	-10.0
		Q1 ; Q3	-24.0 ; 0.0
		Min ; Max	-32 ; 2
	V6 (OLE Month 1)	n	6
		Mean (SD)	-1.3 (23.3)
		Median	7.0
		Q1 ; Q3	-14.0 ; 10.0
		Min ; Max	-42 ; 24
	V7 (OLE Month 2)	n	3
		Mean (SD)	2.7 (33.5)
		Median	20.0
		Q1 ; Q3	-36.0 ; 24.0
		Min ; Max	-36 ; 24
	V8 (OLE Month 3)	n	3
		Mean (SD)	-4.0 (40.1)
		Median	-8.0
		Q1 ; Q3	-42.0 ; 38.0
		Min ; Max	-42 ; 38

Source: Listing 14.2

Baseline is defined as the last available measurements obtained during the screening period,
prior to first IMP dose administration during DB period.

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14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
QT Interval (msec)	V11 (OLE Month 12)	n	2
		Mean (SD)	-16.0 (5.7)
		Median	-16.0
		Q1 ; Q3	-20.0 ; -12.0
		Min ; Max	-20 ; -12
	V12 (End of Taper after OLE period)	n	1
		Mean (SD)	-38.0
		Median	-38.0
		Q1 ; Q3	-38.0 ; -38.0
		Min ; Max	-38 ; -38
QTcB (msec)	V5 (OLE Week 2)	n	6
		Mean (SD)	2.5 (9.3)
		Median	2.5
		Q1 ; Q3	2.0 ; 8.0
		Min ; Max	-14 ; 14
	V6 (OLE Month 1)	n	6
		Mean (SD)	-1.0 (10.5)
		Median	2.5
		Q1 ; Q3	-13.0 ; 7.0
		Min ; Max	-15 ; 10

Source: Listing 14.2

Baseline is defined as the last available measurements obtained during the screening period,
prior to first IMP dose administration during DB period.

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14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
QTcB (msec)	V7 (OLE Month 2)	n	3
		Mean (SD)	1.0 (12.5)
		Median	5.0
		Q1 ; Q3	-13.0 ; 11.0
		Min ; Max	-13 ; 11
	V8 (OLE Month 3)	n	3
		Mean (SD)	1.3 (5.8)
		Median	-2.0
		Q1 ; Q3	-2.0 ; 8.0
		Min ; Max	-2 ; 8
	V11 (OLE Month 12)	n	2
		Mean (SD)	-7.5 (21.9)
		Median	-7.5
		Q1 ; Q3	-23.0 ; 8.0
		Min ; Max	-23 ; 8
	V12 (End of Taper after OLE period)	n	1
		Mean (SD)	-9.0
		Median	-9.0
		Q1 ; Q3	-9.0 ; -9.0
		Min ; Max	-9 ; -9

Source: Listing 14.2

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prior to first IMP dose administration during DB period.

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14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Ventricular Rate (bpm)	V5 (OLE Week 2)	n	6
		Mean (SD)	6.0 (8.2)
		Median	6.0
		Q1 ; Q3	1.0 ; 10.0
		Min ; Max	-5 ; 18
	V6 (OLE Month 1)	n	6
		Mean (SD)	-0.5 (9.8)
		Median	-2.0
		Q1 ; Q3	-8.0 ; 0.0
		Min ; Max	-9 ; 18
	V7 (OLE Month 2)	n	3
		Mean (SD)	-1.0 (16.1)
		Median	-6.0
		Q1 ; Q3	-14.0 ; 17.0
		Min ; Max	-14 ; 17
	V8 (OLE Month 3)	n	3
		Mean (SD)	2.0 (15.5)
		Median	3.0
		Q1 ; Q3	-14.0 ; 17.0
		Min ; Max	-14 ; 17

Source: Listing 14.2

Baseline is defined as the last available measurements obtained during the screening period,
prior to first IMP dose administration during DB period.

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14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

Parameter (Unit)	Visit	Statistics	Overall (N=6)
Ventricular Rate (bpm)	V11 (OLE Month 12)	n	2
		Mean (SD)	4.5 (12.0)
		Median	4.5
		Q1 ; Q3	-4.0 ; 13.0
		Min ; Max	-4 ; 13
	V12 (End of Taper after OLE period)	n	1
		Mean (SD)	11.0
		Median	11.0
		Q1 ; Q3	11.0 ; 11.0
		Min ; Max	11 ; 11

Source: Listing 14.2

Baseline is defined as the last available measurements obtained during the screening period,
prior to first IMP dose administration during DB period.

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