

Table 14.3.5.2 Pain assessment at the site of injection and at the site of surgery (Safety set)

Parameter	Time Point	Pain Assessment ¹	Safety Set			Overall N=45 n (%)
			30 mg N=15 n (%)	40 mg N=15 n (%)	50 mg N=15 n (%)	
Pain at the Injection Site	Immediately after regression of spinal block	0	15 (100.0)	15 (100.0)	15 (100.0)	45 (100.0)
		1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		2	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		4	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		5	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		6	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		7	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		8	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		9	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		10	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain at the Injection Site	Discharge	0	15 (100.0)	15 (100.0)	15 (100.0)	45 (100.0)
		1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		2	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		4	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		5	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		6	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		7	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 14.3.5.2 Pain assessment at the site of injection and at the site of surgery (Safety set)

Parameter	Time Point	Pain Assessment ¹	Safety Set			Overall N=45 n (%)
			30 mg N=15 n (%)	40 mg N=15 n (%)	50 mg N=15 n (%)	
		8	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		9	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		10	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain at the Injection Site	Day 2	0	13 (86.7)	12 (80.0)	12 (80.0)	37 (82.2)
		1	1 (6.7)	1 (6.7)	2 (13.3)	4 (8.9)
		2	0 (0.0)	1 (6.7)	0 (0.0)	1 (2.2)
		3	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		4	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		5	1 (6.7)	0 (0.0)	1 (6.7)	2 (4.4)
		6	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		7	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		8	0 (0.0)	1 (6.7)	0 (0.0)	1 (2.2)
		9	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		10	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain at the Injection Site	Day 7±1	0	15 (100.0)	14 (93.3)	15 (100.0)	44 (97.8)
		1	0 (0.0)	1 (6.7)	0 (0.0)	1 (2.2)
		2	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		4	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 14.3.5.2 Pain assessment at the site of injection and at the site of surgery (Safety set)

Parameter	Time Point	Pain Assessment ¹	Safety Set			Overall N=45 n (%)
			30 mg N=15 n (%)	40 mg N=15 n (%)	50 mg N=15 n (%)	
		5	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		6	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		7	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		8	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		9	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		10	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain at the Surgery Site	Immediately after regression of spinal block	0	6 (40.0)	4 (26.7)	3 (20.0)	13 (28.9)
		1	1 (6.7)	1 (6.7)	0 (0.0)	2 (4.4)
		2	1 (6.7)	3 (20.0)	4 (26.7)	8 (17.8)
		3	1 (6.7)	1 (6.7)	2 (13.3)	4 (8.9)
		4	4 (26.7)	3 (20.0)	2 (13.3)	9 (20.0)
		5	1 (6.7)	2 (13.3)	2 (13.3)	5 (11.1)
		6	0 (0.0)	1 (6.7)	1 (6.7)	2 (4.4)
		7	1 (6.7)	0 (0.0)	0 (0.0)	1 (2.2)
		8	0 (0.0)	0 (0.0)	1 (6.7)	1 (2.2)
		9	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain at the Surgery Site	Discharge	0	8 (53.3)	5 (33.3)	4 (26.7)	17 (37.8)
		1	4 (26.7)	2 (13.3)	0 (0.0)	6 (13.3)

Table 14.3.5.2 Pain assessment at the site of injection and at the site of surgery (Safety set)

Parameter	Time Point	Pain Assessment ¹	Safety Set			Overall N=45 n (%)
			30 mg N=15 n (%)	40 mg N=15 n (%)	50 mg N=15 n (%)	
		2	0 (0.0)	3 (20.0)	4 (26.7)	7 (15.6)
		3	3 (20.0)	4 (26.7)	7 (46.7)	14 (31.1)
		4	0 (0.0)	1 (6.7)	0 (0.0)	1 (2.2)
		5	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		6	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		7	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		8	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		9	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		10	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain at the Surgery Site	Day 2	0	5 (33.3)	7 (46.7)	8 (53.3)	20 (44.4)
		1	1 (6.7)	2 (13.3)	0 (0.0)	3 (6.7)
		2	3 (20.0)	2 (13.3)	1 (6.7)	6 (13.3)
		3	3 (20.0)	1 (6.7)	2 (13.3)	6 (13.3)
		4	0 (0.0)	2 (13.3)	1 (6.7)	3 (6.7)
		5	2 (13.3)	0 (0.0)	1 (6.7)	3 (6.7)
		6	0 (0.0)	0 (0.0)	2 (13.3)	2 (4.4)
		7	1 (6.7)	1 (6.7)	0 (0.0)	2 (4.4)
		8	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		9	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		10	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 14.3.5.2 Pain assessment at the site of injection and at the site of surgery (Safety set)

Parameter	Time Point	Pain Assessment ¹	Safety Set			Overall N=45 n (%)
			30 mg N=15 n (%)	40 mg N=15 n (%)	50 mg N=15 n (%)	
Pain at the Surgery Site	Day 7±1	0	11 (73.3)	14 (93.3)	12 (80.0)	37 (82.2)
		1	1 (6.7)	1 (6.7)	1 (6.7)	3 (6.7)
		2	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3	3 (20.0)	0 (0.0)	0 (0.0)	3 (6.7)
		4	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		5	0 (0.0)	0 (0.0)	2 (13.3)	2 (4.4)
		6	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		7	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		8	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		9	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		10	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Note: Subjects are summarised according to the dose level of the product they actually received

The denominator for calculating the proportions is the number of subjects in each dose level and overall in the safety set

Note 1: Pain was assessed according to a numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain)

Source: [Listing 16.2.9.3](#) - Pain assessment at the site of injection and at the site of surgery

Program: Tables\c122-qs-03-tbl.sas