

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

| Parameter                  | Time Point                                   | Pain<br>Assessment <sup>1</sup> | Safety Set<br>Chloroprocaine 1% |                        |                        | Overall<br>N=45<br>n (%) |
|----------------------------|--|---------------------------------|---------------------------------|------------------------|------------------------|--------------------------|
|                            |  |                                 | 30 mg<br>N=15<br>n (%)          | 40 mg<br>N=15<br>n (%) | 50 mg<br>N=15<br>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 <sup>1</sup> | Safety Set<br>Chloroprocaine 1% |                        |                        | Overall<br>N=45<br>n (%) |
|----------------------------|------------|------------------------------|---------------------------------|------------------------|------------------------|--------------------------|
|                            |            |                              | 30 mg<br>N=15<br>n (%)          | 40 mg<br>N=15<br>n (%) | 50 mg<br>N=15<br>n (%) |                          |
| Pain at the Injection Site | Day 2      | 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)                  |
|                            |            | 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<br>Assessment <sup>1</sup> | Safety Set<br>Chloroprocaine 1% |                        |                        | Overall<br>N=45<br>n (%) |
|--------------------------|--|---------------------------------|---------------------------------|------------------------|------------------------|--------------------------|
|                          |  |                                 | 30 mg<br>N=15<br>n (%)          | 40 mg<br>N=15<br>n (%) | 50 mg<br>N=15<br>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)                  |
|                          |  | 10                              | 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<br>Assessment <sup>1</sup> | Safety Set<br>Chloroprocaine 1% |                        |                        | Overall<br>N=45<br>n (%) |
|--------------------------|------------|---------------------------------|---------------------------------|------------------------|------------------------|--------------------------|
|                          |            |                                 | 30 mg<br>N=15<br>n (%)          | 40 mg<br>N=15<br>n (%) | 50 mg<br>N=15<br>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 <sup>1</sup> | Safety Set<br>Chloroprocaine 1% |                        |                        | Overall<br>N=45<br>n (%) |
|--------------------------|------------|------------------------------|---------------------------------|------------------------|------------------------|--------------------------|
|                          |            |                              | 30 mg<br>N=15<br>n (%)          | 40 mg<br>N=15<br>n (%) | 50 mg<br>N=15<br>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