DESCRIPTION:

In Table 6, the adverse events for Naropin are broken down by gender.

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Female N (%)</th>
<th>Male N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (%)</td>
<td>N (%)</td>
<td></td>
</tr>
<tr>
<td>Bradycardia</td>
<td>29 (11.3)</td>
<td>58 (19.5)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>33 (1.1)</td>
<td>17 (0.7)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>12 (3)</td>
<td>4 (1.1)</td>
</tr>
<tr>
<td>Hypotension</td>
<td>27 (1.1)</td>
<td>8 (0.3)</td>
</tr>
<tr>
<td>Nausea</td>
<td>29 (11.3)</td>
<td>58 (19.5)</td>
</tr>
<tr>
<td>Nervousness</td>
<td>6 (0.2)</td>
<td>2 (0.1)</td>
</tr>
<tr>
<td>Paresthesia</td>
<td>11 (0.5)</td>
<td>10 (0.4)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>16 (4)</td>
<td>5 (1.1)</td>
</tr>
<tr>
<td>Rash</td>
<td>18 (1.1)</td>
<td>13 (0.5)</td>
</tr>
</tbody>
</table>

Naropin-induced bradycardia is generally related to high plasma levels encountered in regional anesthesia. In an observational study, the incidence of bradycardia was 0.3% of all patients receiving regional or local anesthesia.

In addition to the adverse events reported in Table 4, the following adverse events were reported for Naropin:

- Hypotension: 1.7% of patients receiving Naropin
- Bradycardia: 1.1% of patients receiving Naropin
- Dizziness: 0.3% of patients receiving Naropin
- Fatigue: 0.2% of patients receiving Naropin
- Nausea: 1.1% of patients receiving Naropin
- Nervousness: 0.5% of patients receiving Naropin
- Paresthesia: 0.2% of patients receiving Naropin
- Pruritus: 0.4% of patients receiving Naropin
- Rash: 0.5% of patients receiving Naropin

These adverse events are generally dose-related and due to high plasma levels that may result from overdosage, rapid absorption from the injection site, discontinuation of or from unusual transient tachycardia of the local anesthetic solution. In addition, some dialysis-related toxicity, unintended subcutaneous injection of drug during the intended performance of lumbar epidural block or nerve blocks near the vertebral canal (especially in the head and neck region) may result in underdose in some areas (Total on “High” side). Allergic type reactions are rare and may occur as a result of sensitivity to the local anesthetic (see Allergic Reactions).

Naropin is also available as follows:

- Naropin® Single Dose Vials: Product No. 127863, NDC No. 63323-286-31, 150 mg/30 mL (5 mg/mL), 30 mL fill, in a 30 mL single dose vial Sterile-Pak, in boxes of 5.
- Naropin® Single Dose Vials: Product No. 127862, NDC No. 63323-286-23, 100 mg/20 mL (5 mg/mL), 20 mL fill, in a 20 mL single dose vial, in packages of 25.
- Naropin® 5 mg/mL: Product No. 127860, NDC No. 63323-285-20, 40 mg/20 mL (2 mg/mL), 20 mL, in a 20 mL single dose vial.
- Naropin® 10 mg/mL: Product No. 127861, NDC No. 63323-285-10, 80 mg/40 mL (2 mg/mL), 40 mL, in a 40 mL single dose vial.
- Naropin® 20 mg/mL: Product No. 127852, NDC No. 63323-285-01, 120 mg/60 mL (2 mg/mL), 60 mL, in a 60 mL single dose vial.
- Naropin® 30 mg/mL: Product No. 127853, NDC No. 63323-285-00, 180 mg/90 mL (2 mg/mL), 90 mL, in a 90 mL single dose vial.
- Naropin® 50 mg/mL: Product No. 127854, 63323-285-02, 240 mg/120 mL (2 mg/mL), 120 mL, in a 120 mL single dose vial.
- Naropin® 60 mg/mL: Product No. 127855, NDC No. 63323-285-03, 240 mg/120 mL (2 mg/mL), 120 mL, in a 120 mL single dose vial.
- Naropin® 70 mg/mL: Product No. 127856, NDC No. 63323-285-04, 240 mg/120 mL (2 mg/mL), 120 mL, in a 120 mL single dose vial.
- Naropin® 80 mg/mL: Product No. 127857, NDC No. 63323-285-05, 240 mg/120 mL (2 mg/mL), 120 mL, in a 120 mL single dose vial.
- Naropin® 90 mg/mL: Product No. 127858, NDC No. 63323-285-06, 240 mg/120 mL (2 mg/mL), 120 mL, in a 120 mL single dose vial.
- Naropin® 100 mg/mL: Product No. 127859, NDC No. 63323-285-07, 240 mg/120 mL (2 mg/mL), 120 mL, in a 120 mL single dose vial.
- Naropin® 120 mg/mL: Product No. 127864, NDC No. 63323-286-40, 360 mg/180 mL (2 mg/mL), 180 mL, in a 180 mL single dose vial.
- Naropin® 150 mg/mL: Product No. 127865, NDC No. 63323-286-41, 450 mg/225 mL (2 mg/mL), 225 mL, in a 225 mL single dose vial.
- Naropin® 180 mg/mL: Product No. 127866, NDC No. 63323-286-42, 540 mg/270 mL (2 mg/mL), 270 mL, in a 270 mL single dose vial.
- Naropin® 200 mg/mL: Product No. 127867, NDC No. 63323-286-43, 600 mg/300 mL (2 mg/mL), 300 mL, in a 300 mL single dose vial.
- Naropin® 250 mg/mL: Product No. 127868, NDC No. 63323-286-44, 750 mg/375 mL (2 mg/mL), 375 mL, in a 375 mL single dose vial.
- Naropin® 300 mg/mL: Product No. 127869, NDC No. 63323-286-45, 900 mg/450 mL (2 mg/mL), 450 mL, in a 450 mL single dose vial.
- Naropin® 350 mg/mL: Product No. 127870, NDC No. 63323-286-46, 1050 mg/525 mL (2 mg/mL), 525 mL, in a 525 mL single dose vial.
- Naropin® 400 mg/mL: Product No. 127871, NDC No. 63323-286-47, 1200 mg/600 mL (2 mg/mL), 600 mL, in a 600 mL single dose vial.
- Naropin® 450 mg/mL: Product No. 127872, NDC No. 63323-286-48, 1350 mg/675 mL (2 mg/mL), 675 mL, in a 675 mL single dose vial.
- Naropin® 500 mg/mL: Product No. 127873, NDC No. 63323-286-49, 1500 mg/750 mL (2 mg/mL), 750 mL, in a 750 mL single dose vial.