Norditropin® (somatropin injection)
Pronunciation: nor-dee-TROE-pin (soe-mah-TROE-pin)

Indications:
Norditropin® is a recombinant human growth hormone indicated for:

- the treatment of children with:
  - growth failure due to inadequate secretion of endogenous growth hormone
  - short stature associated with Noonan Syndrome
  - short stature associated with Turner Syndrome
  - short stature born small for gestational age (SGA) with no catch-up growth by age 2-4 years
  - Idiopathic Short Stature (ISS)
  - Growth failure due to Prader-Willi Syndrome (PWS)

- The replacement of endogenous growth hormone in adults with growth hormone deficiency (GHD) who meet either of the following two criteria: 1) Adult Onset: Patients who have growth hormone deficiency, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; or 2) Childhood Onset: Patients who were growth hormone deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes.1

Storage and Stability for Norditropin®1

<table>
<thead>
<tr>
<th>Norditropin® FlexPro®</th>
<th>Before Use (unopened)</th>
<th>In-use (after 1st injection)</th>
<th>In-use (after 1st injection)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Strength</td>
<td>Storage Requirement</td>
<td>Storage Option 1 (Refrigeration)</td>
<td>Storage Option 2 (Room temperature)</td>
</tr>
<tr>
<td>5 mg/1.5 mL</td>
<td>2-8°C/36-46°F Good until expiration date</td>
<td>2-8°C/36-46°F Use within 4 weeks</td>
<td>Up to 25°C/77°F Use within 3 weeks</td>
</tr>
<tr>
<td>10 mg/1.5 mL</td>
<td>2-8°C/36-46°F Good until expiration date</td>
<td>2-8°C/36-46°F Use within 4 weeks</td>
<td>Up to 25°C/77°F Use within 3 weeks</td>
</tr>
<tr>
<td>15 mg/1.5 mL</td>
<td>2-8°C/36-46°F Good until expiration date</td>
<td>2-8°C/36-46°F Use within 4 weeks</td>
<td>Up to 25°C/77°F Use within 3 weeks</td>
</tr>
<tr>
<td>30 mg/3 mL</td>
<td>2-8°C/36-46°F Good until expiration date</td>
<td>2-8°C/36-46°F Use within 4 weeks</td>
<td>Use within 3 weeks</td>
</tr>
</tbody>
</table>

FDA Approval of FlexPro® 30 mg/3.0 mL Pen: January 23, 2015 (Launched: April 13, 2015)
- Norditropin® FlexPro® is now available as 5 mg, 10 mg, 15 mg and 30 mg prefilled, multi-dose pens.1
- FlexPro® device includes the following key features: end-of-dose “click” (indicating full selected dose has been ejected), internal dose dial (no thumb reach required in order to press the dosing button), different dialing sounds (indicating the direction in which the patient is dialing), numbers on the dose window with black text on a white background (easy readability)

FDA Approval of PenMate® Device: June 12, 2015 (Launched: Q4 2015)
- FlexPro® PenMate® is a device that attaches to Norditropin® FlexPro® 5 mg, 10 mg, or 15 mg prefilled pens to hide the pen needle from view when injecting growth hormone into the skin.

Comparison of Drug Delivery Devices:
- Differences in dosing increments among growth hormone (GH) delivery devices, which may lead to product wastage, were analyzed in a simulation model. This model was developed to assess four modern GH administration devices: NordiFlex®, FlexPro®, NordiPen®, and MiniQuick®.2
  - Patients required average GH doses, per disease state as follows: 613.62mg (GHD), 677.54mg (SGA), and 651.97mg (TS)
  - Product wastage was determined based on percentage of excess GH dosing compared to annual target dose in each indication:
    - GHD: 0.76% FlexPro® 5 mg vs. 5.66% MiniQuick®
    - TS: 0.80% FlexPro® 5 mg vs. 5.05% MiniQuick®
    - SGA: 0.66% FlexPro® 5 mg vs. 5.75% MiniQuick®
  - To ensure that at least the recommended dose was delivered with each simulated injection, every device dosed a volume of GH either equal to or above the target dose.
  - The model used in the study, which calculated excess GH dosing over one year, showed FlexPro® to have the least amount of excess GH administered.
    - FlexPro® 5mg was shown to have the smallest dosing increment (0.025mg) of all the devices tested and was projected to administer doses <1% above target across all indications in the study.
References