Product Specification Sheet
Norditropin® [somatropin (recombinant)]

Trade Unit Product Information				
Brand Name	Norditropin® FlexPro® 5 mg/1.5 mL	Norditropin® FlexPro® 10 mg/1.5 mL	Norditropin® FlexPro® 15 mg/1.5 mL	Norditropin® FlexPro® 30 mg/3 mL
Generic Name	Somatropin (recombinant)	Somatropin (recombinant)	Somatropin (recombinant)	Somatropin (recombinant)
WAC Price	$767.85	$1,535.70	$2,303.55	$4,607.10
Package presentation	1 carton containing: 1 prefilled FlexPro® pen of Norditropin®	1 carton containing: 1 prefilled FlexPro® pen of Norditropin®	1 carton containing: 1 prefilled FlexPro® pen of Norditropin®	1 carton containing: 1 prefilled FlexPro® pen of Norditropin®
List Number	770421	770521	770821	770321
NDC	0169-7704-21	0169-7705-21	0169-7708-21	0169-7703-21
UPC	3 0169 770421 0	3 0169 770521 7	3 0169 770821 8	3 0169 770321 3
Bar Code	3 01697 70421 0	3 01697 70521 7	3 01697 70821 8	3 01697 70321 3
Trade Unit Dimensions (in L x W x H)	6 x 2.5 x 2.25	6 x 2.5 x 2.25	6 x 2.5 x 2.25	6.375 x 1.375 x 2
Trade Unit Weight (lb)	0.133	0.133	0.133	0.15
Storage (Keep unused Norditropin® refrigerated, 36°F-46°F (2°C-8°C), until expiration date)	After first use, store at 36°F to 46°F (2°C to 8°C) for up to 4 weeks or at room temperature (up to 77°F/25°C) for up to 3 weeks	After first use, store at 36°F to 46°F (2°C to 8°C) for up to 4 weeks or at room temperature (up to 77°F/25°C) for up to 3 weeks	After first use, store at 36°F to 46°F (2°C to 8°C) for up to 4 weeks or at room temperature (up to 77°F/25°C) for up to 3 weeks	After first use, store at 36°F to 46°F (2°C to 8°C) for up to 4 weeks or at room temperature (up to 77°F/25°C) for up to 3 weeks

Indications and Usage

Norditropin® (somatropin) injection is indicated for the treatment of pediatric patients with:

- growth failure due to inadequate secretion of endogenous growth hormone (GH)
- 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 to 4 years of age
- Idiopathic Short Stature (ISS), height standard deviation score (SDS) <-2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range
- growth failure due to Prader-Willi syndrome (PWS)

Norditropin® is also indicated for the replacement of endogenous GH in adults with growth hormone deficiency (GHD)

Important Safety Information

Contraindications

Norditropin® is contraindicated in patients with:

- **Acute critical illness** after open heart surgery, abdominal surgery, or multiple accidental trauma, or those with acute respiratory failure due to the risk of increased mortality with use of pharmacologic doses of somatropin
- **Pediatric patients with Prader-Willi syndrome** who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment due to the risk of sudden death
- **Active Malignancy**
- **Hypersensitivity** to Norditropin® or any of its excipients. Systemic hypersensitivity reactions have been reported with postmarketing use of somatropin products
- Active proliferative or severe non-proliferative **diabetic retinopathy**
- Pediatric patients with **closed epiphyses**

Warnings and Precautions

- **Increased mortality in patients with acute critical illness** due to complications following open heart or abdominal surgery or multiple accidental trauma, or those with respiratory failure has been reported.
- **Sudden death in pediatric patients with Prader-Willi Syndrome** has been reported after initiating treatment with somatropin with one or more of the following risk factors: severe obesity, history of upper airway obstruction or sleep apnea, or unidentified respiratory infection. Evaluate patients for signs of upper airway obstruction and sleep apnea before initiation of treatment.
- **Increased risk of neoplasms:** Monitor patients with preexisting tumors for progression or recurrence. In childhood cancer survivors who were treated with radiation to the brain/head for their first neoplasm and who developed subsequent GHD and were treated with somatropin, an increased risk of a second neoplasm, in particular meningiomas, has been reported. Pediatric patients with certain rare genetic causes of short stature have an increased risk of developing malignancies and should be carefully monitored for development of neoplasms. Monitor patients carefully for increased growth, or potential malignant changes, of preexisting nevi.

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Please see additional Important Safety Information on pages 3 and 4.
Please click here for Prescribing Information.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **Glucose intolerance and diabetes mellitus:** Treatment with somatropin may decrease insulin sensitivity, particularly at higher doses. New-onset type 2 diabetes mellitus has been reported. Monitor glucose levels in all patients. Doses of concurrent antidiabetic drugs may require adjustment.
- **Intracranial hypertension** has been reported in a small number of patients, usually within the first 8 weeks of somatropin treatment. Funduscopic examination should be performed before initiating treatment and periodically thereafter.
- **Severe hypersensitivity:** Serious systemic hypersensitivity reactions including anaphylactic reactions and angioedema have been reported with postmarketing use of somatropin products.
- **Fluid retention** in adults (clinically manifesting as edema, arthralgia, myalgia, nerve compression syndromes including carpal tunnel syndrome/ paraesthesias) may frequently occur and is usually transient and dose-dependent.
- **Hypoadrenalism:** Patients who have or are at risk for pituitary hormone deficiency(s) may be at risk for reduced serum cortisol levels and/or unmasking of central (secondary) hypoadrenalism. In addition, patients treated with glucocorticoid replacement for previously diagnosed hypoadrenalism may require an increase in their maintenance or stress doses following initiation of Norditropin® treatment.
- **Hypothyroidism** if undiagnosed/untreated, may prevent an optimal response to Norditropin®, in particular, the growth response in pediatric patients. In patients with GHD, central (secondary) hypothyroidism may first become evident or worsen during somatropin treatment. Periodic thyroid function tests and thyroid hormone replacement therapy should be initiated or adjusted when indicated.
- **Slipped capital femoral epiphysis in pediatric patients** may occur more frequently in patients with endocrine disorders or in patients undergoing rapid growth. Pediatric patients with the onset of a limp or complaints of hip or knee pain should be evaluated.
- **Progression of preexisting scoliosis in pediatric patients** can occur in patients who experience rapid growth. Patients with a history of scoliosis should be monitored for progression.
- **Pancreatitis:** Cases of pancreatitis have been reported. Pancreatitis should be considered in any patient who develops persistent severe abdominal pain.
- **Lipoatrophy:** Tissue atrophy may result when somatropin is administrated subcutaneously at the same site over a long period of time. Rotate injection sites when administering Norditropin® to reduce this risk.

Adverse Reactions

Other common adverse reactions in adults and pediatric patients include: upper respiratory infection, fever, pharyngitis, headache, otitis media, edema, arthralgia, paresthesia, myalgia, peripheral edema, flu syndrome, and impaired glucose tolerance

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Please see additional Important Safety Information on pages 2 and 4.

Please click here for Prescribing Information.

norditropin®
(somatropin) injection
5 mg, 10 mg, 15 mg, 30 mg pens

Drug Reactions

- **Glucocorticoids:** Patients treated with glucocorticoid for hypoadrenalism may require an increase in their maintenance or stress doses following initiation of Norditropin®
- **Pharmacologic Glucocorticoid Therapy and Supraphysiologic Glucocorticoid Treatment:** Adjust glucocorticoid replacement dosing in pediatric patients receiving glucocorticoid treatment to avoid both hypoadrenalism and an inhibitory effect on growth
- **Cytochrome P450-Metabolized Drugs:** Norditropin® may alter the clearance. Monitor carefully if used with Norditropin®
- **Oral Estrogen:** Larger doses of Norditropin® may be required
- **Insulin and/or Other Hypoglycemic Agents:** Dose adjustment of insulin or hypoglycemic agent may be required

Use in Specific Populations

- **Pregnancy and Nursing Mothers:** There are limited data with somatropin use in pregnant women and nursing mothers to inform a drug-associated risk for adverse developmental outcomes.
- **Geriatric Use:** The safety and effectiveness in patients aged 65 and over has not been evaluated in clinical studies.

Direct access to Norditropin® is available by contacting Novo Nordisk at 1-877-NOVO-777 (1-877-668-6777).

Please see additional Important Safety Information on pages 1-3.
Please click here for Prescribing Information.

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Novo Nordisk Inc.,800 Scudders Mill Road, Plainsboro, New Jersey 08536 U.S.A.

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