Frequently Asked Questions

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**

Frequently Asked Questions

Q. What is Norditropin®?

A. Norditropin® (somatropin) for injection is a recombinant human growth hormone synthesized by a special strain of *E. coli* bacteria. It is a polypeptide with an amino acid sequence identical to naturally occurring pituitary growth hormone with a molecular weight of about 22,000 Daltons. Norditropin® is supplied as a sterile solution for subcutaneous use in ready-to-administer prefilled pens.[1]

Q. What is Norditropin® indicated for?

A. Norditropin® 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 and 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).[1]

Q. What is growth hormone deficiency?

A. Growth hormone deficiency (GHD) is a rare disorder characterized by inadequate secretion of GH from the anterior pituitary gland that can occur in children and adults.[2,3] Onset of adult GHD can occur in childhood or adulthood and commonly results from damage to the pituitary gland.[4,5] Childhood-onset GHD has 3 subdivisions-congenital, acquired, or idiopathic. The occurrence of GHD may be isolated or combined with other pituitary hormonal deficits.[2,3] GHD is one of the pathologic causes of short stature and, when diagnosed, can be treated with GH therapy.[2,6]

Q. What is Turner syndrome?

A. Turner syndrome is a rare chromosomal disorder characterized by hypergonadotropic hypogonadism, infertility, short stature, endocrine and metabolic disorders, an increased risk of autoimmune disease, as well as other medical conditions. Turner syndrome only occurs in females and is associated with a completely or partially missing X chromosome. Turner syndrome is one of the most common chromosomal disorders affecting females. Most girls with Turner syndrome are treated with GH therapy to increase adult stature.[7,8]

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Q. What is Noonan syndrome?

A. Noonan syndrome is a common congenital genetic disorder characterized by short stature, face dysmorphology, congenital heart disease, and other comorbidities.[9,10] Patients with Noonan syndrome have a clinical presentation similar to that of patients with Turner syndrome, but Noonan syndrome occurs equally in males and females.[10] Short stature is a common feature of patients with Noonan syndrome, occurring in about 50% to 70% of cases.[9] Improved height velocity in GH-treated children with Noonan syndrome has been demonstrated in short- and long-term studies without significant adverse events.[9,11,12]

Q. What is Prader-Willi syndrome?

A. Prader-Willi syndrome (PWS) is a rare, complex multisystem genetic disorder caused by lack of expression of imprinted genes on the paternally inherited chromosome 15. PWS is characterized by central hypotonia with a poor suck and feeding difficulties and accompanied by failure to thrive, hypogenitalism/hypogonadism, and GHD.[13,14] Short stature is observed in about 90% of children with PWS.[15] Treatment typically includes GH therapy due to the prevalence of GH deficiency in children with PWS.[13]

Q. What is idiopathic short stature?

A. Idiopathic short stature (ISS) is a term used for children who are short due to an unidentifiable cause. ISS is defined as short stature (>2 standard deviation score (SDS) below the mean height for age, gender, and population) in a child without evidence of any systemic, endocrine, nutritional, or chromosomal abnormalities. Most short children are labeled as having ISS because no diagnosis can be made.[16,17]

Q. What is small for gestational age?

A. Small for gestational age (SGA) refers to infants with a birth weight and/or birth length >2 SD below the mean for gestational age.[18,19] Many infants born SGA will experience catch-up growth within the critical 2-year period; however, infants that don't catch-up in growth are more likely to develop metabolic and psychosocial issues and experience disordered growth.[19] Some children born SGA may have persistent short stature due to inadequate catch-up growth within the first 2 years.[18,19] Treatment with GH is indicated in children born SGA who fail to reach appropriate growth velocity by age 2 in the United States.[20,21]

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Q. What is the mechanism of action of Norditropin®?

A. Norditropin® is a recombinant GH that binds to membrane-bound GH receptors in target tissue cells, inducing the production of GH-dependent proteins including insulin-like growth factor 1 (IGF-1), insulin-like growth factor binding protein 3 (IGFBP-3), and acid-labile subunit. Skeletal growth stimulated by Norditropin® increases linear growth rate in most pediatric patients receiving GH replacement therapy. GH-induced metabolic and tissue effects such as protein synthesis, lipolysis, and stimulation of hepatic glucose output may be in direct response to Norditropin® or mediated indirectly by IGF-1.[1]

Q. When did Norditropin receive US Food and Drug Administration (FDA) approval?

A. Norditropin® was FDA approved in 1995 for the treatment of growth failure due to inadequate GH secretion in pediatric patients. On November 1, 2004, the indication was expanded to include adult patients with GHD.[21] In 2007, indications were expanded to include treatment of short stature associated with Turner syndrome and Noonan syndrome in pediatric patients.[22,23] Norditropin® was FDA approved for the indication of treatment of short stature born SGA without catch-up growth by age 2 years to 4 years of age on October 31, 2008.[24] Indications were expanded to include the treatment of ISS and growth failure due to PWS in pediatric patients on February 23, 2018.[25]

Q. What are the ingredients in Norditropin®?

A. Norditropin® is a sterile, clear, and colorless solution containing the active ingredient somatropin and the following excipients: histidine, poloxamer 188, phenol, mannitol, hydrochloric acid/sodium hydroxide (as needed) and water for injection.[1]

Q. What are the most frequently reported adverse reactions of Norditropin®?

A. The most frequent adverse reactions in pediatric patients with growth failure due to inadequate secretion of endogenous GH were headache pharyngitis, otitis media, and fever.[1]

The most frequent adverse reactions in pediatric patients with short stature associated with Noonan syndrome were upper respiratory infection, gastroenteritis, ear infection, and influenza.[1]

The most frequently reported adverse reactions in pediatric patients with short stature associated with Turner syndrome were influenza-like illness, otitis media, upper respiratory tract infection, otitis externa, gastroenteritis, eczema, and impaired fasting glucose.[1]

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The most frequently reported adverse reactions in pediatric patients born SGA with no catch-up growth by 2 to 4 years of age were influenza-like illness, upper respiratory tract infection, bronchitis, gastroenteritis, abdominal pain, otitis media, pharyngitis, arthralgia, headache, gynecomastia, and increased sweating.[1]

The most common adverse reactions in pediatric patients with ISS treated with another somatropin product were upper respiratory tract infection, influenza, tonsilitis, nasopharyngitis, gastroenteritis, headaches, increased appetite, pyrexia, fracture, altered mood, and arthralgia.[1]

Adverse reactions reported in pediatric patients with growth failure due to PWS treated with another somatropin product were edema, aggressiveness, arthralgia, benign intracranial hypertension, hair loss, headache, and myalgia.[1]

Adverse reactions with >10% overall incidence in adult-onset growth hormone deficient patients were peripheral edema (42%), edema (25%), arthralgia (19%), leg edema (15%), myalgia (15%), non-viral infection (13%), paresthesia (11%), and skeletal pain (11%).[1]

Q. Who should not use Norditropin®?

A. Norditropin® is contraindicated in patients with[1]:

- 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 PWS 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

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Q. Who manufactures Norditropin®?

A. Norditropin® is manufactured by Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark.[1]

Q. How is Norditropin® supplied?

A. Norditropin® injection is a clear and colorless solution available as FlexPro® prefilled pens[1]:

- 5 mg/1.5 mL (orange) NDC 0169-7704-21
- 10 mg/1.5 mL (blue) NDC 0169-7705-21
- 15 mg/1.5 mL (green) NDC 0169-7708-21
- 30 mg/3 mL (purple) NDC 0169-7703-21

Q. How is Norditropin® administered?

A. Administer Norditropin® by subcutaneous injection to the back of the upper arm, abdomen, buttocks, or thigh with regular rotation of injection sites to avoid lipoatrophy. Instructions for delivering the dosage are provided in the Prescribing Information and the Patient Information and Instructions for Use leaflets enclosed with the Norditropin® FlexPro® prefilled pen.[1]

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Q. Who can administer Norditropin®?

A. Norditropin® is administered by subcutaneous injection only. Patients or caregivers may administer Norditropin® at home after reading the detailed Instructions for Use that come with Norditropin®. Patients or caregivers should be trained to inject by their health care provider prior to first injection. Norditropin® FlexPro® pens are for use by 1 person only.[1]

Q. How is the Norditropin® FlexPro® pen obtained?

A. Norditropin® FlexPro® pens can be accessed and acquired through specialty pharmacy distributors.

Q. How do I store Norditropin®?

A. New, unused Norditropin® FlexPro® pens must be stored in a refrigerator between 36 °F to 46 °F (2 °C to 8 °C). Do not freeze. Avoid direct light. If Norditropin® has been frozen or in temperatures above 77 °F (25 °C), do not use.[1]

While in use, Norditropin® FlexPro® pens may be stored in a refrigerator between 36 °F to 46 °F (2 °C to 8 °C) and used within 4 weeks or at room temperature no warmer than 77 °F (25 °C) and used within 3 weeks.[1]

Q. Where can I get more information about Norditropin®?

A. More information about Norditropin® can be found at https://www.novomedlink.com/growth-related-disorders/products/treatments/norditropin.html

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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
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- Pediatric patients with **closed epiphyses**

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Important Safety Information (cont'd)

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.
- **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.

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Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **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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Important Safety Information (cont'd)

Drug Interactions

- **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.

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References

1. Norditropin [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; 2020. 2. Dattani MT, Malhotra N. A review of growth hormone deficiency. *Paediatr Child Health.* 2019;29(7):285-292. doi:10.1016/j.paed.2019.04.001 3. Webb EA, Dattani MT. Diagnosis of growth hormone deficiency. *Endocr Dev.* 2010;18:55-66. doi:10.1159/000316127 4. Brod M, Pohlman B, Højbjerre L, Adalsteinsson JE, Rasmussen MH. Impact of adult growth hormone deficiency on daily functioning and well-being. *BMC Res Notes.* 2014;7:813. doi:10.1186/1756-0500-7-813 5. Yuen KCJ, Biller BMK, Radovick S, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Growth Hormone Deficiency in Adults and Patients Transitioning from Pediatric to Adult Care. *Endocr Pract.* 2019;25(11): 1191-1232. doi:10.4158/GL-2019-0405 6. Barstow C, Rerucha C. Evaluation of short and tall stature in children. *Am Fam Physician.* 2015;92(1):43-50 7. Elsheikh M, Dunger DB, Conway GS, Wass JA. Turner's syndrome in adulthood. *Endocr Rev.* 2002;23(1):120-140. doi:10.1210/edrv.23.1.0457 8. Bondy CA; Turner Syndrome Study Group. Care of girls and women with Turner syndrome: a guideline of the Turner Syndrome Study Group. *J Clin Endocrinol Metab.* 2007;92(1):10-25. doi:10.1210/jc.2006-1374 9. Romano AA, Allanson JE, Dahlgren J, et al. Noonan syndrome: clinical features, diagnosis, and management guidelines. *Pediatrics.* 2010;126(4):746-759. doi:10.1542/peds.2009-3207 10. Bhambhani V, Muenke M. Noonan syndrome. *Am Fam Physician.* 2014;89(1):37-43 11. Osio D, Dahlgren J, Wikland KA, Westphal O. Improved final height with long-term growth hormone treatment in Noonan syndrome. *Acta Paediatr.* 2005;94(9):1232-1237. doi:10.1111/j.1651-2227.2005.tb02081 x 12. Allanson JE, Roberts AE. Noonan syndrome. In: Adam MP, Ardinger HH, Pagon RA, et al, eds. *GeneReviews.* University of Washington; 2019. 13. Butler MG, Miller JL, Forster JL. Prader-Willi syndrome—clinical genetics, diagnosis and treatment approaches: an update. *Curr Pediatr Rev.* 2019;15(4):207-244. doi:10.2174/1573396315666190716120925 14. Goldstone AP, Holland AJ, Hauffa BP, Hokken-Koelega AC, Tauber M; speakers contributors at the Second Expert Meeting of the Comprehensive Care of Patients with PWS. Recommendations for the diagnosis and management of Prader-Willi syndrome. *J Clin Endocrinol Metab.* 2008;93(11):4183-4197. doi:10.1210/jc.2008-0649 15. Wasserman M, Mulvihill EM, Ganan-Soto A, Uysal S, Quintos JB. Severe short stature in an adolescent male with Prader-Willi syndrome and congenital adrenal hyperplasia: a therapeutic conundrum. *Case Rep Endocrinol.* 2017;2017:4271978. doi:10.1155/2017/4271978 16. Cohen P, Rogol AD, Deal CL, et al. Consensus statement on the diagnosis and treatment of children with idiopathic short stature: a summary of the Growth Hormone Research Society, the Lawson Wilkins Pediatric Endocrine Society, and the European Society for Paediatric Endocrinology Workshop. *J Clin Endocrinol Metab.* 2008;93(11):4210-4217. doi:10.1210/jc.2008-0509 17. Pedicelli S, Peschiaroli E, Violi E, Cianfarani S. Controversies in the definition and treatment of idiopathic short stature (ISS). *J Clin Res Pediatr Endocrinol.* 2009;1(3):105-115. doi:10.4008/jcrpe.v1i3.53 18. Clayton PE, Cianfarani S, Czernichow P, Johannsson G, Rapaport R, Rogol A. Management of the child born small for gestational age through to adulthood: a consensus statement of the International Societies of Pediatric Endocrinology and the Growth Hormone Research Society. *J Clin Endocrinol Metab.* 2007;92(3):804-810. doi:10.1210/jc.2006-2017 19. Saenger P, Czernichow P, Hughes I, Reiter EO. Small for gestational age: short stature and beyond. *Endocr Rev.* 2007;28(2):219-251. doi:10.1210/er.2006-0039 20. Houk CP, Lee PA. Early diagnosis and treatment referral of children born small for gestational age without catch-up growth are critical for optimal growth outcomes. *Int J Pediatr Endocrinol.* 2012;2012(1):11. doi:10.1186/1687-9856-2012-11 21. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Norditropin NDA 21148/S-007 supplemental approval letter; November 1, 2004. 22. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Norditropin NDA 21148/S-016 supplemental approval letter; May 31, 2007. 23. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Norditropin NDA 21148/S-017 supplemental approval letter; September 20, 2007. 24. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Norditropin NDA 21148/S-023 supplemental approval letter; October 31, 2008. 25. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Norditropin NDA 21148/S-037 and S-038 supplemental approval letter; February 23, 2018.

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