



press release

Health Canada approves Norditropin NordiFlex® - first approved human growth hormone treatment for Noonan syndrome in Canada

Norditropin NordiFlex® is the first and only approved growth hormone product for children with short stature associated with Noonan's syndrome

MISSISSAUGA, ON – June 21, 2021 - Health Canada has approved Norditropin NordiFlex® (somatropin injection) for the treatment of short stature in children associated with Noonan syndrome.^{1,2}

Noonan syndrome is a rare genetic disorder associated with a wide spectrum of congenital abnormalities, including cardiac defects in the majority of these children, distinctive craniofacial features, short stature, developmental delays and other comorbidities. The incidence of Noonan syndrome is estimated to be 1 in 1,000- 2,500 live births and affects both girls and boys equally.

"The medical challenges of Growth Disorders can be overwhelming. Providing patients with effective and convenient choices to manage their condition is essential," said Mike Samad, Medical Director, BioPharmaceuticals, Novo Nordisk Canada Inc. "Since providing the world's first injection system more than 90 years ago, we have been committed to making medication delivery simple and convenient, and to improving disease outcomes and delivering innovative therapies that address unmet disease needs. If a child is not growing as they should, it is important for parents/guardians to talk to their doctor."

Norditropin® is used for the treatment of children with growth failure due to inadequate secretion of growth hormone. It is also used for the treatment of growth delay in short children born small for gestational age (SGA) who failed to show catch-up growth by 2 years of age or later and for the treatment of children with short stature associated with Turner Syndrome. Most recently, Norditropin® was approved for Noonan Syndrome.

The safety profile of Norditropin® was established in Noonan syndrome in one clinical trial that included 51 patients. The proportion of children with adverse events were similar between both dose groups (0.033mg/kg/day and 0.066mg/kg/day). The most common adverse events were signs and symptoms commonly observed in children including general infections, respiratory tract infections, otitis media, eczema and pyrexia. The majority of the adverse events were non-serious, mild or moderate in severity and assessed as unlikely related to trial product. The most common adverse drug reaction (possibly or probably related) was hyperinsulinemia (7.7%) which was in the 0.066 mg/kg/day group. Norditropin®

therapy should be carried out under the guidance of a doctor who is experienced in the diagnosis and management of patients with growth disorders.

About Growth Disorders

Growth hormone is produced naturally by the pituitary gland in the brain. Growth hormone is a messenger to signal growth along with many other important metabolic functions. Some children experience slow growth compared to their siblings and peers due to environmental factors. For other children, their short stature is caused by a medical condition that either slows or stops growth including the inability to produce or secrete enough growth hormone or its effector protein insulin-like growth factor I (IGF-I).

About Recombinant Human Growth Hormone (rhGH)

Recombinant human growth hormone (rhGH) is a biosynthetic human growth hormone used in growth hormone replacement therapy (GHT). It is identical to the natural growth hormone produced by the body and must be administered subcutaneously (under the skin). GHT is used to treat children who are not growing normally due to an underlying medical condition.

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 42,700 people in 80 countries and markets its products in around 170 countries. For more information, visit [novonordisk.ca](#), [Twitter](#), or [YouTube](#).

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Further information

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¹ Norditropin NordiFlex®, Novo Nordisk Canada Inc., [Product Monograph](#), June, 2021

² Norditropin NordiFlex®, Novo Nordisk Canada Inc., [Product Monograph](#), June, 2021