

Novo Nordisk Receives FDA Approval for Norditropin(R) FlexPro(R) for Growth ...

Novo Nordisk announced today that the U.S. Food and Drug Administration (FDA) has approved Norditropin™ FlexPro™ (somatropin rDNA origin injection), a pre-filled injection pen to be used by children and adults with growth hormone disorders. It will be available in the second quarter.

Norditropin™ FlexPro™ has a user friendly design which makes it easy to learn and use, and an audible click that confirms that the medication has left the pen. Norditropin™ FlexPro™ requires no reconstitution and no loading of cartridges. Norditropin™ FlexPro™ is available in 5 mg/1.5 mL, 10 mg/1.5 mL and 15 mg/1.5 mL pens. After first use, the 5 mg/1.5 mL and 10 mg/1.5 mL pens may be left at room temperature for up to three weeks without risk of spoilage.

In a study designed to evaluate the usability of the product, 100 percent of patients found it easy to learn how to use Norditropin™ FlexPro™, while 99 percent of patients found it easy to push the button to dose and 99 percent found it easy to inject their dose.

"Easy to use, growth hormone delivery devices allow patients and health care professionals alike to benefit from the convenience of these pens," said Dr. Pinchas Cohen, professor of pediatrics at the David Geffen School of Medicine at UCLA and chief of endocrinology at the Mattel Children's Hospital at UCLA.

Novo Nordisk introduced Norditropin™ in 1988, the first liquid growth hormone formulation Norditropin™ SimpleXx™ in 1999 and the first prefilled growth hormone pen Norditropin™ NordiFlex™ in 2004. Norditropin™ is used to treat children with growth failure caused by very low or no production of growth hormone and in adults who don't produce enough growth hormone. It is also approved for the treatment of children who have short stature associated with Noonan syndrome, Turner syndrome, and for treatment of children with short stature born small for gestational age with no catch-up growth by age 2-4 years.

The introduction of Norditropin™ FlexPro™ represents the latest advance in growth hormone devices from Novo Nordisk. Patients can receive support and training for Norditropin™ FlexPro™ through the NordiCare™ program.

"We worked hard to make daily injections with Norditropin™ FlexPro™ simple, hoping to help patients achieve their individual treatment goals," said Eddie Williams, Vice President of Biopharmaceuticals at Novo Nordisk. "This approval may provide the thousands of patients with these growth hormone disorders an easy to use and simple treatment option."

About Norditropin™

Norditropin™ (somatropin rDNA origin injection) is used to treat: children who have growth failure because of low or no growth hormone; children who are short (in stature) and who have Noonan syndrome or Turner syndrome; children who are short (in stature) because they were born small (small for gestational age-SGA) and have not caught-up in growth by age 2 to 4 years; and adults who do not make enough growth hormone.

IMPORTANT SAFETY INFORMATION

Do not use Norditropin™ if: you have a critical illness caused by certain types of heart or stomach surgery, trauma or breathing (respiratory) problems; you are a child with Prader-Willi syndrome who is severely obese or has breathing problems including sleep apnea; you have cancer or other tumors; your healthcare provider tells you that you have certain types of eye problems caused by diabetes; you are a child with closed bone growth plates (epiphyses) or you are allergic to any of the ingredients in the medicine.

Before you take Norditropin™, tell your healthcare provider if you: have diabetes; had cancer or any tumor; have any other medical condition; are pregnant or plan to become pregnant; are breast-feeding or plan to breast-feed.

Norditropin™ can cause serious side effects, including: high risk of death in people who have critical illnesses because of heart or stomach surgery, trauma or serious breathing (respiratory) problems; high risk of death in children with Prader-Willi syndrome who are severely obese or have breathing problems including sleep apnea; return of tumor or cancerous growths; high blood sugar (hyperglycemia); increase in pressure in the skull (intracranial hypertension); swollen hands and feet due to fluid retention; decrease in thyroid hormone levels; hip and knee pain or a limp in children (slipped capital femoral epiphysis); worsening of pre-existing curvature of the spine (scoliosis); middle ear infection, hearing problems or ear problems in patients with Turner syndrome.

The most common side effects of NorditropinTM include: headaches, muscle pain, joint stiffness, high blood sugar (hyperglycemia), sugar in your urine (glucosuria), swollen hands and feet due to fluid retention, and redness and itching in the area you inject.

If you have headaches, eye problems, nausea or vomiting, contact your healthcare provider right away.

NorditropinTM may affect how other medicines work, and other medicines may affect how NorditropinTM works so be sure to tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take: glucocorticoid medication, thyroid hormone, insulin or other medicine for diabetes, medicines that are metabolized by the liver (e.g., corticosteroids, sex steroids, anticonvulsants, cyclosporine), or oral estrogen replacement medicine.

For full prescribing information, visit www.norditropin-us.com.

About Novo Nordisk

Headquartered in Denmark, Novo Nordisk is a global healthcare company with 87 years of innovation and leadership in diabetes care. The company also has leading positions within hemophilia care, growth hormone therapy and hormone replacement therapy. For more information, visit novonordisk-us.com

About the Author

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