Norditropin® FlexPro (somatropin) – New indications and updated warnings

- On February 23, 2018, the FDA approved Novo Nordisk's Norditropin FlexPro (somatropin), for the treatment of idiopathic short stature (ISS), height standard deviation score (HSDS) < -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 FlexPro is also approved for the replacement of endogenous growth hormone (GH) in adults with GH deficiency (GHD) and for the treatment of pediatric patients with:

    - Growth failure due to inadequate secretion of endogenous GH
    - Short stature associated with Noonan syndrome
    - Short stature associated with Turner syndrome
    - Short stature born small for gestational age with no catch-up growth by age 2 years to 4 years of age.

- The approval of Norditropin FlexPro for ISS was partly based on an open-label efficacy and safety study of another somatropin product enrolling 105 patients with ISS. Patients were randomized to somatropin 0.033 mg/kg/day or 0.067 mg/kg/day or left untreated.

    - Final HSDS for the 0.033 mg dose vs. untreated was 0.53 (95% CI: 0.20, 0.87; $p < 0.05$).
    - Final HSDS for the 0.067 mg dose vs. untreated was 0.94 (95% CI: 0.63, 1.26; $p < 0.05$).
    - The mean gain in final height was 9.8 cm for females and 5.0 cm for males for both doses combined vs. untreated patients.

- The approval of Norditropin FlexPro for PWS was partly based on two open-label efficacy and safety studies of another somatropin product enrolling 43 patients with PWS.

    - In the first study, linear growth at 12 months was 11.6 ± 2.3 cm for the somatropin-treated patients vs. 5.0 ± 1.2 cm for the untreated control group ($p < 0.05$).
    - In the second study, linear growth at 12 months was 10.7 ± 2.3 cm for the somatropin-treated patients vs. 4.3 ± 1.5 cm for the untreated control group ($p < 0.05$).

- In addition, two warnings were removed from the Norditropin FlexPro drug label:

    - Otitis media and cardiovascular disorders in Turner Syndrome
    - Confirmation of childhood onset adult GHD

- For pediatric patients, the recommended dosage of Norditropin FlexPro should be administered by subcutaneous injection to the back of the upper arm, abdomen, buttocks, or thigh with regular rotation of injection sites to avoid lipoatrophy. Divide the calculated weekly dosage into equal doses given either 6 or 7 days per week as follows:

    - ISS: Up to 0.47 mg/kg/week (up to 0.067 mg/kg/day).
    - PWS: 0.24 mg/kg/week (0.034 mg/kg/day).
    - Individualize dosage for each patient based on the growth response.
    - Assess compliance and evaluate other causes of poor growth such as hypothyroidism, under-nutrition, advanced bone age and antibodies to recombinant human GH if patients experience failure to increase height velocity, particularly during the first year of treatment.

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- Discontinue Norditropin FlexPro for stimulation of linear growth once epiphyseal fusion has occurred.
- Consult Norditropin FlexPro's drug label for dosage recommendations for other pediatric indications and for adult dosing.

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