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Reproductive Endocrinology

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A Multicenter, Open Label, Variable Dose, Two-Arm, Pilot Paediatric Phase 1 Pk Study To Evaluate 4.5% Testosterone Nasal Gel In Hypogonadal Boys

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Introduction: Testosterone treatment is regularly required by adolescent boys with hypogonadism.

Aim: To evaluate the pharmacokinetics of a nasal testosterone gel, which is available for adult men with hypogonadism, in adolescents.

Methods: Open-label, variable-dose, non-randomized, 3-treatment crossover study of testosterone nasal gel 4.5% w/w (Natesto™). Subjects were hypogonadal adolescent boys between the ages of 12.0–17.9 years. Biochemical analyses were performed by Acerus Pharma.

Summary and Conclusions: Testosterone nasal gel 4.5% w/w (Natesto™) represents a safe and acceptable method of administering testosterone to hypogonadal adolescents. Based on feedback from both patients and investigators, the nasal gel was well tolerated by patients, and it was felt that children would be able to administer this independently.

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