

APPROPRIATE USE OF iGRO

Use of the Actual versus Predicted Growth Response

The Actual versus Predicted Growth Response utilizes published prediction models to provide a visual representation of a patient's actual growth response versus their predicted growth response to growth hormone (GH) treatment according to the published models. The response to GH therapy varies by diagnosis and is relatively greater in patients with idiopathic growth hormone deficiency (IGHD) than in patients with Turner syndrome (TS) or those who are small for gestational age (SGA). There is also significant variability in the responsiveness of individuals even within these different diagnostic categories. It is important to note that the growth prediction models used in iGRO for growth hormone deficiency can only be applied in patients with IGHD.

Variations in responsiveness may be influenced by factors such as inappropriate diagnosis, the presence of endocrine, nutritional or systemic disorders, lack of compliance with treatment or impaired sensitivity to GH. Physicians must utilize their own knowledge and judgment when assessing the growth response of their patients and making adjustments to their plan of treatment.

Limitations of the Actual versus Predicted Growth Response

Use of the actual versus predicted growth response is limited by a variety of factors. Growth is a complex process and many known and unknown factors can affect the growth response to GH treatment. As such, the variables found to be associated with growth response in the prediction models, all of which are based on multiple regression analysis of data from KIGS explain 30 to 70% of the variability in growth response, and in some cases closer to 30% (30-70% for IGHD, 30-68% for TS, 30-52% for SGA).

Further, multiple regression analysis of data from large populations of patients can provide important information about those populations, but their significance for the individual patient may be limited as the predicted value for an individual patient can deviate considerably from the observed value (e.g. for the 1st year IGHD model the 95 % confidence interval for an individual prediction is ± 2.6 cm). In addition, the prediction models do not take into consideration the presence of subgroups within a specific diagnostic category, such as in TS where subgroups exist based on karyotype. Given these limitations, it is important that the prediction models are used by experts with knowledge of statistics and experience in GH treatment in children.

GH dosing

Any dose of GH prescribed should be in accordance with the relevant product SmPC.

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