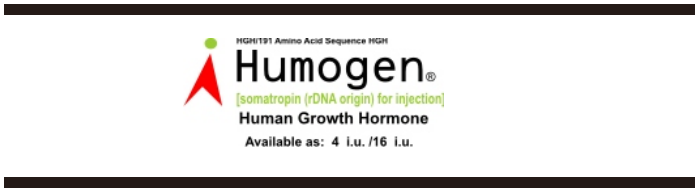

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Humogen is a human growth hormone produced by recombinant DNA technology. Humogen has 191 amino acid residues and a molecular weight of 22,125 daltons. Its amino acid sequence and structure are identical to the dominant form of human pituitary growth hormone. Humogen is produced by a mammalian cell line (mouse C127) that has been modified by the addition of the human growth hormone gene. Humogen, with the correct three-dimensional configuration, is secreted directly through the cell membrane into the cell-culture medium for collection and purification.

Humogen is a highly purified preparation. Biological potency is determined by measuring the increase in body weight induced in hypophysectomized rats.

Humogen is a sterile, non-pyrogenic, white, lyophilized powder intended for subcutaneous or intramuscular injection after reconstitution with Bacteriostatic Water for Injection, USP (0.9% Benzyl Alcohol).

The quantitative composition per vial is:

5 mg vial:
Each vial contains 5 mg somatropin, 34.2 mg sucrose and 1.16 mg O-phosphoric acid. The pH is adjusted with sodium hydroxide or O-phosphoric acid.

8.8 mg vial:
Each vial contains 8.8 mg somatropin, 60.2 mg sucrose and 2.05 mg O-phosphoric acid. The pH is adjusted with sodium hydroxide or O-phosphoric acid.
The diluent is Bacteriostatic Water for Injection, USP containing 0.9% Benzyl Alcohol added as an antimicrobial preservative.

INDICATIONS
Pediatric Patients

Humogen [somatropin (rDNA origin) for injection] is indicated for the long-term treatment of children with growth failure due to inadequate secretion of endogenous growth hormone.
Adult Patients

Humogen [somatropin (rDNA origin) for injection] is indicated for replacement of endogenous growth hormone in adults with growth hormone deficiency who meet either of the following two criteria:

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Adult Onset: Patients who have growth hormone deficiency, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; or

Childhood Onset: Patients who were growth hormone deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes.

In general, confirmation of the diagnosis of adult growth hormone deficiency in both groups usually requires an appropriate growth hormone stimulation test. However, confirmatory growth hormone stimulation testing may not be required in patients with congenital/genetic growth hormone deficiency or multiple pituitary hormone deficiencies due to organic disease.

DOSAGE AND ADMINISTRATION

Pediatric Growth Hormone Deficiency (GHD)

Humogen [somatropin (rDNA origin) for injection] dosage and schedule of administration should be individualized for each patient. The recommended weekly dosage is 0.18 mg/kg of body weight. It should be divided into equal doses given either on 3 alternate days, 6 times per week or daily. The subcutaneous route of administration is preferable; intramuscular injection is also acceptable.

Treatment with Humogen of growth failure due to growth hormone deficiency should be discontinued when the epiphyses are fused. Patients who fail to respond adequately while on Humogen therapy should be evaluated to determine the cause of unresponsiveness.

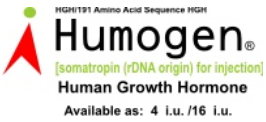
Adult Growth Hormone Deficiency (GHD)

Based on the weight-based dosing utilized in the original pivotal study described herein, the recommended dosage at the start of therapy is not more than 0.005 mg/kg given as a daily subcutaneous injection. The dosage may be increased to not more than 0.01 mg/kg/day after 4 weeks according to individual patient requirements. Clinical response, side effects, and determination of age-and gender-adjusted serum IGF-I levels may be used as guidance in dose titration.

Stability And Storage

Before Reconstitution - Humogen [somatropin (rDNA origin) for injection] should be stored at room temperature (15o-30oC/59o-86oF). Expiration dates are stated on the labels.

After Reconstitution - Humogen 5 mg and 8.8 mg vials reconstituted with Bacteriostatic Water for Injection, USP (0.9% Benzyl Alcohol) provided should be stored under refrigeration (2°-8°C/36°-46°F) for up to 14 days.



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Humogen click.easy® cartridges reconstituted with the diluent containing 0.3% (w/v) metacresol in Sterile Water for Injection should be stored under refrigeration (2°-8°C/36°-46°F) for up to 21 days.

Avoid freezing reconstituted vials or cartridges of Humogen.

WARNINGS

There have been reports of fatalities after initiating therapy with somatropin in pediatric patients with Prader-Willi syndrome who had one or more of the following risk factors: severe obesity, history of upper airway obstruction or sleep apnea, or unidentified respiratory infection. Male patients with one or more of these factors may be at greater risk than females. Patients with Prader-Willi syndrome should be evaluated for signs of upper airway obstruction and sleep apnea before initiation of treatment with somatropin. If, during treatment with somatropin, patients show signs of upper airway obstruction (including onset of or increased snoring) and/or new onset sleep apnea, treatment should be interrupted. All patients with Prader-Willi syndrome treated with somatropin should also have effective weight control and be monitored for signs of respiratory infection, which should be diagnosed as early as possible and treated aggressively (see CONTRAINDICATIONS). Unless patients with Prader-Willi syndrome also have a diagnosis of growth hormone deficiency, Humogen is not indicated for the long term treatment of pediatric patients who have growth failure due to genetically confirmed Prader-Willi syndrome.

CONTRAINDICATIONS

Humogen is contraindicated in patients with a known hypersensitivity to somatropin or any of its excipients.

Humogen reconstituted with Bacteriostatic Water for Injection, USP (0.9% Benzyl Alcohol) should not be administered to patients with a known sensitivity to Benzyl Alcohol (see WARNINGS).

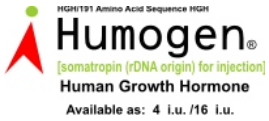
Somatropin should not be used for growth promotion in pediatric patients with closed epiphyses.

Somatropin is contraindicated in patients with active proliferative or severe non-proliferative diabetic retinopathy.

Presentation

Somatropin Injection	Each 1 ml Injection

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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Information for Health Care Professionals

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