

## Recombinant Human Growth Hormone for Injection

- major components: recombinant human growth hormone and excipients.
- Molecular formula: C990H1528N262O300S7, for the 191 amino acid protein
- weight: 22125D
- This product is a white lyophilized powder

### Indications

- used due to endogenous growth hormone deficiency caused by the slow growth of children;
- Treatment for severe burns;
- has been clear for the hypothalamus - pituitary disease and growth hormone deficiency caused by two different growth hormone growth hormone stimulation test confirmed a significant deficiency.

### Specifications

- 10IU/3.7mg/1.0ml / bottle

### Dosage

- to promote children's growth and the dose varies, the recommended dose for the 0.1-0.15IU/kg body weight / day once daily, subcutaneous injection, treatment for 3 months to 3 years, or as directed.
- Recommended for severe burn treatment dose 0.2-0.4IU/kg weight / day once daily subcutaneous injection. Treatment usually about 2 weeks.
- replacement therapy for adult dosage must be adjusted from person to person. Starting from the low dose is usually recommended, such as 0.5 units per day (0.17 mg) or large amount of 0.02 units / kg body weight / day, equivalent to 0.007 mg / kg body weight / day; after one month of treatment results, the dose was gradually adjusted to 0.04 units / kg body weight / day, equivalent to 0.013 mg / kg body weight / day. Serum insulin-like growth factor I (IGF-I) dose levels can be used as reference. Dose was reduced with age.

### Adverse reactions

- Growth hormone can cause a transient hyperglycemia, usually with prolonged treatment or after stopping back to normal.
- 1% in clinical trials of short stature children have side effects, common transient local injection site reactions (pain, numbness, redness, etc.) and symptoms of fluid retention (peripheral edema, joint pain or muscle pain), these side effects earlier, the incidence decreased with prolonged drug use, rare affect daily activities.
- Long-term injection of recombinant human growth hormone in the body caused by a small number of patients produce antibodies, antibody binding is low, no definite clinical significance, but if the results failed to meet the expected growth, then there may be antibodies, antibody binding than 2mg / L, then may affect the efficacy.

### Taboo

- after epiphyseal closure has been completely disabled in the growth-promoting treatment;
- serious systemic infections in critically ill patients with acute shock in the body during the disabled.

### Notes

- Under the guidance of doctors for the diagnosis of patients.
- diabetes may need to adjust the dose of anti-diabetic drugs.

- use of corticosteroids may also inhibit the growth-promoting effect of growth hormone, so the patient suffering from ACTH deficiency should adjust the dosage of corticosteroids in order to avoid its inhibitory effect on growth hormone production. (See Drug Interactions)
- a small number of patients that may occur during growth hormone treatment of thyroid dysfunction, should be promptly corrected, to avoid affecting the efficacy of growth hormone, so patients should check thyroid function periodically, if necessary, given thyroxine supplement.
- suffering from endocrine disorders (including growth hormone deficiency) may occur in patients of femoral head epiphyseal detachment, growth hormone treatment in the event of claudication of the phenomenon should be noted that assessment.
- sometimes can lead to excessive growth hormone insulin status, whether the patient must pay attention to the phenomenon of reduced glucose tolerance.
- blood glucose during treatment than 10mmol / L, insulin therapy is required. For use 150IU / day or more insulin to control blood sugar can not and should stop using this product.
- changes in the injection site should always avoid fat atrophy.

#### Pregnant and lactating women drug

- unfit for use.

#### Pediatric Use

- children for growth hormone in the pharmacology and toxicology, pharmacokinetics and no significant difference between adults, according to body weight safe to use.

#### Medication in elderly patients

- There is no system of clinical research with the elderly

#### Drug Interactions

- At the same time use of corticosteroids may inhibit the hormone response, so in the treatment of glucocorticoid hormone normally not more than a considerable amount of 10-15mg of hydrocortisone / m body surface area. While non-androgenic steroid use could be further enhanced growth rate.

#### Drug overdose

- no reported cases of acute drug overdose. However, more than the recommended dose can cause adverse reactions, drug overdoses cause low blood sugar will first start, and then high blood sugar. Long-term overdose may result in symptoms of acromegaly and symptoms and other reactions related with the growth hormone excess.

#### Pharmacology and toxicology

- human growth hormone (hGH) is from the anterior pituitary, growth hormone containing eosinophilic granules (GH) secretion by cells, composed of 191 amino acid peptide hormone. This product is secreted by E. coli expression of recombinant technology to produce recombinant human growth hormone (rhGH), its amino acid sequence of human growth hormone content and the same. This product is in Escherichia coli (E. Coli) in the synthesis. Hormone synthesis by the former (prehormone) carried out. The former is a naturally occurring hormone in bacteria, and connected with the signal peptide hormone composition. Before the hormone in the inner wall of the cell division of bacteria, the natural growth hormone release and the end products into the wall of the same film gap, and then to collect only the destruction of cell wall and the cell wall intact, very few bacterial protein contamination to ensure the final product.

- secreted recombinant human growth hormone (rhGH) has the same human endogenous growth hormone effects side epiphyseal cartilage cells to stimulate differentiation, proliferation,

stromal cells to stimulate cartilage growth, stimulation of osteoblast differentiation, proliferation, causing linear growth acceleration and bone wider. Promote the general protein synthesis, post-traumatic surgery to correct the negative nitrogen balance, correct moderate to severe infection and cirrhosis due to hypoproteinemia; stimulate the immune globulin synthesis, stimulate the lymphatic tissue, macrophages and lymphocytes to enhance resistance to infection; stimulate collagen burn wounds and surgical incisions fibroblast cells, macrophages, proliferation, accelerate wound healing, promoting myocardial protein synthesis, increased myocardial contractility, reduced myocardial oxygen consumption, regulate fat metabolism, reduce serum cholesterol, low density lipoprotein levels; supplement inadequate or lack of growth hormone, regulate fat metabolism in adults, bone metabolism, heart and kidney function.

#### Pharmacokinetics

- According to the literature, subcutaneous or intramuscular administration of the same effect in two ways, subcutaneous than intramuscular injection will usually lead to higher serum GH concentrations, but the insulin-like growth factor I (IGF-I) concentrations are the same. GH is usually slower absorption, plasma GH concentration is usually 3-5 hours after the administration reached a peak; clear half-life is generally 2-3 hours, GH by the liver, renal clearance, and faster than children, adults; excluded from the urine is not directly The extremely small amount of GH metabolism.

- Nearly all circulating in the blood are associated with high affinity GH GH binding protein (hGHBP) combine to make this complex half-life of GH in serum is extended, in the time of the day, select the injection will not affect the serum of different GH concentrations.

#### Period

- 24 months

#### Storage

- 2 ~ 8 °C from light and transport, can be stored for 7 days at room temperature, dissolved in liquid can be placed in the refrigerator for 2 ~ 8 °C for 72 hours.

#### Packaging

- Control of antibiotic vial; 10 bottles / box