Instructions for Recombinant Human Interferon γ for Injections

Please read the instructions carefully and follow your doctor's orders.

[**Product name**]

Generic name: Recombinant Human Interferon γ for Injections

Product name: gamma

English name: Recombinant Human Interferon γ for Injections

Chinese pinyin: Zhu She Yong Chong Zu Ren Gan Rao Su Ga Ma

[**Ingredients**] The main component of recombinant Interferon γ is produced by fermentation, separation and high degree of purification of escherichia coli, which contains a high efficient expression of the interferon gamma gene.

Molecular weight: 16.8KD ±10%;

Other ingredients: Human blood albumin, mannitol, phosphate buffer (disodium phosphate, dihydrogen phosphate).

[Traits] Milky white freeze-dried powder.

[**Indications**] Rheumatiod arthritis, hepatic fibrosis.

[**Specifications**] 1. A single bottle containing 1 million international units (IU), specific activity >1.5 Xl07IU/mg.

2. A single bottle containing 2 million international units (IU), specific activity >1.5 Xl07IU/mg.

[**Use and Dosage**] Rheumatoid arthritis: This product should be used under the guidance of clinicians. Administer this product by subcutaneous or intramuscular injection after dissolving with 1ml sterilized water. In the first 3 to 4 days, administer 50 international units (IU) daily. If there are no obvious adverse reactions, increase the dosage to 1 million IU a day. From the beginning of the second month, administer 150 to 2 million IU every other day. The whole course of treatment lasts 3 months.

Hepatic fibrosis: This product should be used under the guidance of clinicians. Administer this product by subcutaneous or intramuscular injections after dissolving with 1ml sterilized water. In the first 3 months, administer 100 international units (IU) daily. In the last 6 months, administer 100 million IU every other day. The whole course of treatment lasts 9 months.

[Adverse Reaction] Fever is the most common adverse reaction. It often occurs at the start of the drug use phase, about 3 to 4 hours after injection. For most cases, temperature is below 38°C. In rare cases when it's 38 ° C and above, the fever will regress itself after several hours. Generally, after 2 to 4 days of medication, there will be no fever responses. Other adverse reactions are fatigue, discomfort, headache, muscle pain, joint pain, loss of appetite, nausea, etc.

Common laboratory abnormalities are granular leukopenia and thrombocytopenia, usually temporary and reversible, and can be recovered from without interference. In case of severe side effects when the patient cannot tolerate, reduce the dosage or stop use, then give symptomatic treatment accordingly.

[**Contraindication**]

1. Patients who are allergic to products made of interferon or escherichia coli;

2.Patients with angina pectoris, history of myocardial infarction and other serious cardiovascular diseases;

3. Patients suffering from other serious diseases that cannot tolerate the possible adverse effects of this drug.

4. Patients with epilepsy and other central nervous system dysfunction.

[**Pre-cautions**]

If there is any obvious allergic reaction, especially for the allergy of antibiotics, use this product with caution. If an allergic reaction occurs in the process, the medicine should be stopped immediately and treatment should be given accordingly.

Check the bottle carefully before use. If there are cracks and breakage, you can't use them. After adding water for injection, the product should be in good dissolubility, and should not be used when there are undissolved lumps or floccus.

[**Usage for pregnant women or lactating women**] This product has not been used widely for pregnant women or lactating women. It should be used with great caution and under the close observation of doctors.

[**Usage for children**] This product has not been used widely for children. It should be used with great caution and under the close observation of doctors, especially for younger children.

[**Usage for the elderly**] No significant differences were found in efficacy and safety for different age groups. This product can be used for elderly patients.

[**Drug interaction**] No systematic studies were done to determine how human recombinant interferon gamma interacts with other drugs. In clinical application, do not use this product with drugs that inhibit bone marrow hematopoietic function.

[**Drug overdose**] According to the results of phase I clinical trials, subjects can tolerate different dosage of up to 4 million IU/day.

[**Pharmacology and toxicology**] Interferon γ has a strong immune regulating function which can strengthen the function of antigen presenting cells, accelerate the reduction of immune complexes and increase phagocytosis function. It can also have a two-way adjustment function for lymphocytes, increase antibody dependent cell toxic reaction and raise HLA class II antigen expression for some immune active cells. Interferon γ has a strong inhibitory effect on the activation, proliferation and extracellular matrix secretion of hepatic stellate cells (HSC), and it can also inhibit collagen synthesis and promote collagen degradation.

No toxic reaction was found in the safety tests on guinea pigs and mice.

In the acute toxicity test on im mice, acute toxicity LDso > 2Xl08IU/m2.

In general pharmacological experiments, there was no adverse reaction to the cardiovascular system, respiratory system and mouse nervous system in rats. In the long term toxicity test, toxic reaction was not found in im ffistar rats and Beagled within 3 months of drug use.

[**Pharmacokinetic**] The study on 10 volunteers who received 2 million IU via subcutaneous injections indicates that after human recombinant Interferon γ is absorbed slowly, and more than 89% of the dose can be absorbed. After subcutaneous injections, the average removal period was 9.35 hours, the peak concentration of the highest peak occurred after 3.4 hours, and the peak concentration was 37.4 IUM.

A pharmacokinetic study suggests that this product can be administered once a day.

[**Storage**] Keep in 2 ~ 8 ° C, and avoid light.

[**Packaging**] Sirrine bottle, rubber plug, 1 x 5 bottles/box

[**Validity**] 24 months

[**Executive standard**] China pharmacopoeia, 2015 edition 3

[**Approval number**] 1 million IU/bottle, national drug approval no. S10980084;
2 million IU/bottle, national drug approval no. S20020040

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