Interferon Alpha 2b
Shaferon
3 million IU/mL
5 million IU/mL
6 million IU/mL
Solution for Injection
(I.M./I.V)

FORMULATION:
Each mL contains Interferon Alpha 2b (Human)………………… 3 million IU
Each mL contains Interferon Alpha 2b (Human)………………… 5 million IU
Each mL contains Interferon Alpha 2b (Human)………………… 6 million IU

DESCRIPTION:
Interferon Alpha 2b is colorless transparent liquid, without visible undissolved particles.

PHARMACOLOGICAL PROPERTIES

Pharmacology
Interferon Alpha 2b has antiviral, antitumor, restraining germ reproduction and immunomodulatory properties. Once bound to the cell membrane, interferons initiate a complex sequence of intracellular events.

In vitro studies demonstrated that these include the induction of certain enzymes, inhibition of virus replication in virus-infected cells, immunomodulating activities such as enhancement of the phagocytic activity of macrophages and augmentation of the specific cytotoxicity of lymphocytes for target cells, and the activity of natural killer cells.

Toxicology
Acute toxicity: Dosage of 10³-10⁴ times to human treatment was injected to rat intraperitoneally and intravenously, no acute poisoning symptoms appeared and no mice died.

Long-term toxicity: Dosage of 10⁵, 10⁶, 10⁷ times to human treatment was injected to mice and rabbit intramuscularly, and the course is 6 months and 3 months, respectively. General station, weight and performance of mice dose not appear abnormality. There is not any toxicity reactions found in the rabbits during these 3 months. Furthermore, no alteration due to toxicity of medicine was found after pathology examination of organs.

PHARMACOKINETICS

Following intramuscular or subcutaneous injections, the maximum serum Recombinant Human Interferon concentrations were occurred 3 to 6 hours after administration, and the elimination half-life of Recombinant Human Interferon α-2b was approximately 4 to 12 hours. The kidney is the main site of interferon catabolism, while the other site is bile excretion. Bioavailability exceeds 80%.

INDICATIONS

Interferon Alpha 2b is indicated against viruses and are active against malignant neoplasms and have immunomodulating effect. Also used to treat patients with chronic hepatitis B, several malignant neoplasms including AIDS-related Kaposi’s sarcoma, hairy-cell leukemia, chronic myeloid leukemia, carcinoid tumours, melanoma, myeloma, and in condylomata acuminata

ADMINISTRATION AND DOSAGE

Interferon Alpha 2b is administered intramuscular, subcutaneous or intratumoral injection.

1. Chronic viral hepatitis B: 3-5MIU once daily, administered subcutaneously or intramuscularly, continuously for 4 weeks. Then three times a week for more than 16 weeks. The physician may adjust dosage according to patient’s response and tolerance to medication.

2. Acute and Chronic viral hepatitis C: 3-6MIU once daily, administered subcutaneously or intramuscularly, continuously for 4 weeks. Then three times a week for more than 16 weeks. The physician may adjust dosage according to patient’s response and tolerance to medication.

3. Herpes zoster: 1MIU administered intramuscularly once daily, continuously for 6 days. And taking orally acyclovir once at the same time. The physician may adjust dosage according to patient’s response and tolerance to medication.

4. Condylomata acuminata: 1-3MIU administered intramuscularly, continuously for 4 weeks. Another method is 3MIU injected in the base of wart, simultaneously treating with laser or electrotherapeutics.

5. Haery cell leukaemia: 2-8MIU/m² administered once daily, continuously for not less than 3 months. The physician may adjust dosage according to patient’s response and tolerance to medication. The response is achieved usually after 1-2 months of treatment. Long-term palliation may be achieved by intermittence treatment of Recombinant Human Interferon α-2b.

6. Chronic myelogenous leukaemia: 3-5MIU/m² once daily administered intramuscularly, also can be administered simultaneously with chemotherapy medicines such as hydroxy arsenide and Atra-C. All patients with complete hematological responses should continue injection every other day. The cytogeneric changes may be achieved in 9-10 months. The physician may adjust dosage according to patient’s response and tolerance to medication.

7. Multiple myeloma: 3-5MIU/m² administered intramuscularly three times a week, simultaneously with chemotherapy such as VMCP. The physician may adjust dosage or combine with other drugs according to patient’s response and tolerance to medication.

8. Malignant melanoma: 6MIU administered intramuscularly three times a week, simultaneously with chemotherapy.

9. Lymphoma: 3-5MIU/m² administered intramuscularly three times a week, simultaneously with chemotherapy such as CHVP. The physician may gradually increase dosage according to patient’s response and tolerance to medication until reach the maximum dosage for 8-12 weeks. The treatment should be maintained for 12 months unless disease progresses rapidly or server intolerance occurs. The physician may adjust dosage according to patient’s response and tolerance to medication.

10. Kidney carcinoma: 6MIU administered intramuscularly three times a week, simultaneously with chemotherapy.

11. AIDS related Kaposi’s sarcoma: 50MIU/m³ infused daily, continuously for 5 days. The infusion time should not be less than 30 minutes. Next course is started after at least a 9-day-break.

12. Basal cell carcinoma: 5MIU infused intratumoraly three times a week for three weeks.

13. Ovary carcinoma: 5-6MIU administered intramuscularly three times a week, simultaneously with chemotherapy.

ADVERSE REACTIONS EFFECTS

The most commonly adverse reactions is fever or fever with “flu-like” symptoms, such as chill, fatigue, headache and myalgia. These effects will alleviated or reversible by taking antipyretic analgesic.
Usually appear in the first administered week and disappear with 48 hours after injection. Common haematological test abnormalities include reduction in leucocyte and platelet counts and increase of ALT. Other reported adverse reactions include: anorexia, diarrhea, nausea, hypertension, vomiting, arthralgia, impaired consciousness, confusion, dizziness, ataxia, paresthesia, anxiety, depression, nervousness, somnolence, pruritis, alopecia transient, rash and itch. Rarely side effects include: leg cramps, constipation, insomnia, herpetic eruptions, cold sores (non-herpetic), rash, urticaria, hot flushes, tachycardia, epistaxis, stomatitis, paralytic ileus, coagulation disorder (elevated prothrombin time and partial thromboplastin time), agitation, coughing, furunculosis and abnormal vision.

Very rarely occurring adverse reaction include: postural hypotension, erythema, thyroid dysfunction, pruritus, rash, urticaria, hot flushes, injection site reaction and inflammation, oculomotor paralysis, nasal congestion, flatulence, increased saliva, hyperglycemia and ulcerative stomatitis.

CONTRAINDICATIONS
Interferon Alpha 2b is contraindicated in the patients with history of hypersensitivity to interferon α-2b, and any components of the preparation. Patients with severe heart diseases, renal dysfunction, epilepsy, CNS dysfunction or other serious diseases should not use Recombinant Human Interferon α-2b.

PRECAUTIONS
Interferon Alpha 2b is colorless transparent liquid, and injection with turbidity or deposit can not be used. If not used up, the residue can not be stored for later use, because activity will decline and injection may be contaminated. If the pre-filled syringe is destroyed or injection is overdue, the injection should not be used.

PREGNANCY AND LACTATION
There are no adequate and well-controlled studies in pregnant women. Recombinant Human Interferon α-2b therapy should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

PEDIATRIC
There are no adequate and well-controlled studies in pediatrics. Recombinant Human Interferon α-2b should be used carefully only if the potential benefit justifies the potential risk.

SENIILE
Aged patients with heart disease or cancer should check ECG before administration and during treating course, and the physician may adjust dosage or stop administration.

DRUG INTERACTIONS
Interferon may alter activity of some enzymes, especially reducing activity of cytochrome enzyme P450, so infecting metabolism of some medicines including simetidine, warfarin, aminophylline, diazepam, propranolol, etc.

When Recombinant human interferon α-2b combined with medicines having effects on CNS, the medicines will interact with each other.

OVERDOSAGE
There are not reports about overdosage of Recombinant Human Interferon α-2b yet. People who administer high dosage Recombinant Human Interferon α-2b would feel seriously fatigue and feeble.

AVAILABILITY
3 million IU in pre-filled syringe and vial/box; 5 million IU and 6 million IU in pre-filled syringe/box

EXPIRATION PERIOD
Expiration period of the preparation is 2 years.

STORAGE
Store between 2-8℃. Do not freeze.

CAUTION: FOODS, DRUGS, DEVICES and COSMETICS ACT prohibit dispensing without prescription.
Manufactured By:
BEIJING KAWIN TECHNOLOGY SHARE-HOLDING CO., LTD.
No. 6 East Rongjing Street, BDA, Beijing 100176, P.R. of China
Imported & Distributed By:
SAHAR INTERNATIONAL TRADING INC.
354 Aguirre Ave., Phase III BF Homes,
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