Interferon alfa-2a, recombinant

**Intramuscular Injection**

**Description**

Interferon alfa-2a, recombinant refers to the biological activities of Interferon alfa-2a, recombinant are species-restricted; i.e., play important roles in antitumor and antiviral activity.

**Potency**

The potency of Interferon alfa-2a, recombinant is expressed as M.I.U. (milliunits) per dose.

**Dosing**

**Intramuscular Injection**

- **Intramuscular Injection**
  - **Adults**
    - For the treatment of chronic hepatitis C, a dose of 3 MIU once daily for 24 weeks is recommended.
    - For the treatment of AIDS-related Kaposi's sarcoma, a dose of 3 MIU three times weekly for 12 months is recommended.
  - **Cytogenetic Response Rates**
    - In study DM84-38, 15 patients proceeded to BMT. Roferon-A treatment significantly increased the likelihood of response compared to the chemotherapy control group (48 patients in study MI400 proceeded to BMT).
  - **Clinical Response Rates**
    - In trials in which Roferon-A was administered for 6 months, 6 MIU, 3 MIU, and 1.5 MIU each week, the respective clinical response rates were 19% (24/125), 9% (11/125), and 4% (5/125).

**Adverse Effects**

- **Hematologic**
  - Leukopenia and elevation of hepatic enzymes occurred frequently but were rarely associated with clinical manifestations. Patients with chronic hepatitis C who have liver disease, severe renal or hepatic disease, seizure disorders and/or compromised immune status should be monitored closely for the development of adverse effects.
- **Cardiovascular**
  - Patients with a history of cardiovascular disease, severe renal or hepatic disease, seizure disorders and/or compromised immune status should be monitored closely for the development of adverse effects.
- **Respiratory**
  - Patients with a history of respiratory disease, severe renal or hepatic disease, seizure disorders and/or compromised immune status should be monitored closely for the development of adverse effects.
- **Gastrointestinal**
  - Patients with a history of gastrointestinal disease, severe renal or hepatic disease, seizure disorders and/or compromised immune status should be monitored closely for the development of adverse effects.
- **Other**
  - Patients with a history of other disease, severe renal or hepatic disease, seizure disorders and/or compromised immune status should be monitored closely for the development of adverse effects.

**Contraindications**

- **Intramuscular Injection**
  - Patients who are hypersensitive to human interferons or the preservatives benzyl alcohol or polysorbate 80 should not receive Roferon-A. Patients who have received Roferon-A in a prior treatment regimen should not receive it again.
  - Patients with a history of severe preexisting cardiac, hepatic, or renal disease should be monitored closely for the development of adverse effects.
  - Patients who are immunosuppressed transplant recipients should not be treated with Roferon-A.

**Precautions**

- **Intramuscular Injection**
  - Patients who are immunosuppressed transplant recipients should not be treated with Roferon-A.

**Interactions**

- **Intramuscular Injection**
  - Patients who are immunosuppressed transplant recipients should not be treated with Roferon-A.

**Monitoring Laboratory Tests**

- **Intramuscular Injection**
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**Storage**

- **Intramuscular Injection**
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**Patient Information**

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**References**

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**Notes**

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Roferon-A (Interferon alfa-2a, recombinant) ROFERON

Roferon-A has not been tested for its carcinogenic potential.

When given to nonhuman primates, Roferon-A has caused hepatocellular changes in rhesus monkeys. These monkeys returned to a normal hepatic appearance after cessation of Roferon-A administration. There are no adequate and well-controlled studies in pregnant women.

- Macaca mulatta (rhesus monkey). Nonpregnant rhesus females treated with 22.8 MIU of Interferon alfa-2a, recombinant in order to provide the delivery of 1.9 mmol/L and serum phosphorus (1.6 mmol/L) and serum calcium (2.4 mmol/L) levels. The following infrequent adverse events have been reported in one or more of the clinical studies: Alopecia, anemia, aspartate aminotransferase (SGOT), alkaline phosphatase, hypothyroidism, thyroid disease, diabetes, transaminase (SGPT), luteinizing hormones, hypercalceremia, rash, injection site irritation, rashes, injection site inflammation, injection site edema, flu-like symptoms, chest pain, shortness of breath, fatigue, myalgia, peripheral edema, hypothyroidism, polyuria, hyponatremia, anemia, neutrophilic leukocytosis, blood platelet abnormalities, liver function tests, injection site pain, injection site swelling, urticaria, abdominal pain, arthralgia, back pain, chest pain, conjunctivitis (4%), menstrual irregularity (2%) and visual disturbance (4%).

For patients with hairy cell leukemia, the percentage of patients with complete hematologic response with 1.9 MIU three times a week (tiw) of Roferon-A over 6 months is 91% without the need for additional therapy. Such patients should be hospitalized for observation and appropriate supportive care, including hydration and antiemetics or sedatives if required. If the adverse events continue or are unresponsive to supportive care, drug discontinuation is recommended, and the patients should be observed periodically for the next 6 months. When such patients are not treated, the disease is progressive, with a median survival of 12 months and a 2-year survival of 50%.

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For patients with chronic myelogenous leukemia, the percentage of patients with complete hematologic response with 1.9 MIU three times a week (tiw) of Roferon-A is 48% without the need for additional therapy. Such patients should be hospitalized for observation and appropriate supportive care, including hydration and antiemetics or sedatives if required. If the adverse events continue or are unresponsive to supportive care, drug discontinuation is recommended, and the patients should be observed periodically for the next 6 months. When such patients are not treated, the disease is progressive, with a median survival of 12 months and a 2-year survival of 50%.

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