INTERFERON ALFA-2B

CLASS: Interferon

INDICATIONS:

Patients ≥1 year of age: Chronic hepatitis B

Patients ≥3 years of age: Chronic hepatitis C (in combination with ribavirin)

Patients ≥18 years of age: Condyloma acuminata, chronic hepatitis B, chronic hepatitis C, hairy cell leukemia, malignant melanoma (high-risk of recurrence), AIDS-related Kaposi's sarcoma, follicular non-Hodgkin lymphoma

AVAILABLE DOSAGE FROM THE HOSPITAL:

TRADE NAMES:

DOSAGE:

- **Dosing: Adult**
  Details concerning dosing in combination regimens should also be consulted. Consider premedication with acetaminophen prior to administration to reduce the incidence of some adverse reactions. Not all dosage forms and strengths are appropriate for all indications; refer to product labeling for details.

  Hairy cell leukemia: I.M., SubQ: 2 million units/m2 3 times weekly for up to 6 months (may continue treatment with sustained treatment response); discontinue for disease progression or failure to respond after 6 months

  Lymphoma (follicular): SubQ: 5 million units 3 times weekly for up to 18 months

  Malignant melanoma: Induction: 20 million units/m2 I.V. for 5 consecutive days per week for 4 weeks, followed by maintenance dosing of 10 million units/m2 SubQ 3 times weekly for 48 weeks

  AIDS-related Kaposi's sarcoma: I.M., SubQ: 30 million units/m2 3 times weekly; continue until disease progression or until maximal response has been achieved after 16 weeks

  Chronic hepatitis B: I.M., SubQ: 5 million units/ daily or 10 million units 3 times weekly for 16 weeks

Chronic hepatitis C: I.M., SubQ: 3 million units 3 times weekly. In patients with normalization of ALT at 16 weeks, continue treatment (if tolerated) for 18-24 months; consider discontinuation if normalization does not occur at 16 weeks. Note: May be used in combination therapy with ribavirin in previously untreated patients or in patients who relapse following alpha interferon therapy.

Condyloma acuminata: Intralesionally: 1 million units/lesion (maximum: 5 lesions per treatment) 3 times weekly (on alternate days) for 3 weeks. May administer a second course at 12-16 weeks

- **Dosing: Geriatric**
  Refer to adult dosing.

- **Dosing: Renal Impairment**

  Combination therapy with ribavirin (hepatitis C) should not be used in patients with reduced renal function (Clcr <50 mL/minute).

- **Dosing: Hepatic Impairment**

  No dosage adjustment provided in manufacturer's labeling.

- **Dosing: Adjustment for Toxicity**

  Hematologic toxicity (also refer to indication specified adjustments below): ANC <500/mm3 or platelets < 25,000/mm3: Discontinue treatment.

  Hypersensitivity reaction (acute, serious), ophthalmic disorders (new or worsening), thyroid abnormality development (which cannot be normalized with medication), signs or symptoms of liver failure: Discontinue treatment.

  Liver function abnormality, pulmonary infiltrate development, evidence of pulmonary function impairment, or autoimmune disorder development, triglycerides >1000 mg/dL: Monitor closely and discontinue if appropriate.

  Neuropsychiatric disorders (during treatment):

  Clinical depression or other psychiatric problem: Monitor closely during and for 6 months after treatment.

  Severe depression or other psychiatric disorder: Discontinue treatment.

  Persistent or worsening psychiatric symptoms, suicidal ideation, aggression towards others: Discontinue treatment and follow with appropriate psychiatric intervention.

  Manufacturer-recommended adjustments, listed according to indication:

  Lymphoma (follicular):

Neutrophils >1000/mm3 to <1500/mm3: Reduce dose by 50%; may re-escalate to starting dose when neutrophils return to >1500/mm3

Severe toxicity (neutrophils <1000/mm3 or platelets <50,000/mm3): Temporarily withhold.

AST >5 times ULN or serum creatinine >2 mg/dL: Permanently discontinue.

Hairy cell leukemia:

Platelet count <50,000/mm3: Do not administer intramuscularly (administer SubQ instead).

Severe toxicity: Reduce dose by 50% or temporarily withhold and resume with 50% dose reduction; permanently discontinue if persistent or recurrent severe toxicity is noted.

Chronic hepatitis B:

WBC <1500/mm3, granulocytes <750/mm3, or platelet count <50,000/mm3, or other laboratory abnormality or severe adverse reaction: Reduce dose by 50%; may re-escalate to starting dose upon resolution of hematologic toxicity. Discontinue for persistent intolerance.

WBC <1000/mm3, granulocytes <500/mm3, or platelet count <25,000/mm3: Permanently discontinue

Chronic hepatitis C: Severe toxicity: Reduce dose by 50% or temporarily withhold until subsides; permanently discontinue for persistent toxicities after dosage reduction.

AIDS-related Kaposi sarcoma: Severe toxicity: Reduce dose by 50% or temporarily withhold; may resume at reduced dose with toxicity resolution; permanently discontinue for persistent/recurrent toxicities.

Malignant melanoma (induction and maintenance):

Severe toxicity including neutrophils >250/mm3 to <500/mm3 or ALT/AST >5-10 times ULN: Temporarily withhold; resume with a 50% dose reduction when adverse reaction abates.

Neutrophils <250/mm3, ALT/AST >10 times ULN, or severe/persistent adverse reactions: Permanently discontinue.

COMMON SIDE EFFECT:

Note: In a majority of patients, a flu-like syndrome (fever, chills, tachycardia, malaise, myalgia, headache), occurs within 1-2 hours of administration; may last up to 24 hours and may be dose limiting.

>10%:

Cardiovascular: Chest pain (≤28%)

Central nervous system: Fatigue (8% to 96%), fever (34% to 94%; more common in children), headache (21% to 62%), chills (≤54%), depression (3% to 40%; grades 3/4: 2%), somnolence (≤33%), dizziness (≤24%), irritability (≤22%), pain (≤18%), amnesia (≤14%), concentration impaired (≤14%), malaise (≤14%), confusion (≤12%), insomnia (≤12%)

Dermatologic: Alopecia (≤38%), rash (≤25%), pruritus (≤11%)

Endocrine & metabolic: Amenorrhea (≤12%)

Gastrointestinal: Anorexia (1% to 69%), nausea, (17% to 66%), diarrhea (2% to 45%), xerostomia (≤28%), vomiting (children 27%; adults 7% to 10%), taste alteration (≤24%), abdominal pain (1% to 23%), constipation (≤14%), gingivitis (≤14%), weight loss (<1% to 13%)

Hematologic: Neutropenia (≤92%; grade 4: 1% to 4%), leukopenia (≤68%), anemia (≤32%), thrombocytopenia (≤15%)

Hepatic: AST increased (≤63%; grades 3/4: 14%), ALT increased (≤15%), pain (upper right quadrant: up to 15%); alkaline phosphatase increased (≤13%)

Local: Injection site reaction (≤20%)

Neuromuscular & skeletal: Myalgia (28% to 75%), weakness (≤63%), rigors (≤42%), paresthesia (1% to 21%), skeletal pain (≤21%), arthralgia (≤19%), back pain (≤19%)

Renal: BUN increased (≤12%)

Respiratory: Dyspnea (≤34%), cough (≤31%), pharyngitis (≤31%), sinusitis (≤21%)

Miscellaneous: Flu-like syndrome (≤79%), diaphoresis (1% to 21%), moniliasis (≤17%)

PREGNANCY RISK FACTORS: C / X in combination with ribavirin