Roferon–A is an interferon. Following activation of the interferon, multiple effects can be detected including induction of gene transcription. It inhibits cellular growth, alters the state of cellular differentiation, interferes with oncogene expression, alters cell surface antigen expression, increases phagocytic activity of macrophages, and augments cytotoxicity of lymphocytes for target cells.

Pre-Authorization Criteria:

Roferon–A is used to treat Hairy cell leukemia, AIDS-related Kaposi's sarcoma, chronic hepatitis C in patients age >18 years. It is also used to treat chronic myelogenous leukemia (CML), Philadelphia chromosome positive in children and adults. Its unlabeled or investigational use includes the following: adjuvant therapy for malignant melanoma, AIDS-related thrombocytopenia, cutaneous ulcerations of Behcet's disease, brain tumors, metastatic ileal carcinoid tumors, cervical and colorectal cancers, genital warts, idiopathic mixed cryoglobulinemia, hemangioma, hepatitis D, hepatocellular carcinoma, idiopathic hypereosinophilic syndrome, mycosis fungoides, Sezary syndrome, low-grade non-Hodgkin's lymphoma, macular degeneration, multiple myeloma, renal cell carcinoma, basal and squamous cell skin cancer, essential thrombocythemia, and cutaneous T-cell lymphoma.

VCHCP requires that Roferon be prescribed by an oncologist.

MONITORING PARAMETERS — Baseline ophthalmologic exam should be performed in all patients, with periodic reassessment in patients with impairment. Patients with thyroid dysfunction should be monitored by TSH levels at baseline and every 3 months during therapy.

Chronic hepatitis C: Monitor ALT (at baseline, after 2 weeks, and monthly thereafter) and HCV-RNA (particularly in first 3 months of therapy)

CML/hairy cell leukemia: Hematologic monitoring should be performed monthly
DOSING: ADULTS — Refer to individual protocols. See Lexi-Comp Online™

DOSING: PEDIATRIC — Refer to individual protocols. See Lexi-Comp Online™

DOSING: ELDERLY — Refer to adult dosing.

DOSING: RENAL IMPAIRMENT — Not removed by hemodialysis

ADMINISTRATION — SubQ administration is suggested for those who are at risk for bleeding or are thrombocytopenic; rotate SubQ injection site; patient should be well hydrated

CONTRAINDICATIONS — Hypersensitivity to alfa interferon, benzyl alcohol, or any component of the formulation; autoimmune hepatitis; visceral AIDS-related Kaposi’s sarcoma associated with rapidly-progressing or life-threatening disease; hepatic decompensation (Child-Pugh Class B or C)

WARNINGS / PRECAUTIONS — Use caution in patients with a history of depression. May cause severe psychiatric adverse events (psychosis, mania, depression, suicidal behavior/ideation) in patients with and without previous psychiatric symptoms; careful neuropsychiatric monitoring is required during therapy. Use with caution in patients with seizure disorders, brain metastases, or compromised CNS function. Higher doses in the elderly or in malignancies other than hairy cell leukemia may result in severe obtundation.

Use caution in patients with autoimmune diseases; development or exacerbation of autoimmune diseases has been reported. Use caution in patients with pre-existing cardiac disease (ischemic or thromboembolic), arrhythmias, renal impairment (Clcr<50 mL/minute), mild hepatic impairment, or myelosuppression. Also use caution in patients receiving therapeutic immunosuppression. May cause thyroid dysfunction or hyperglycemia, use caution in patients with diabetes or pre-existing thyroid disease. Pulmonary dysfunction may be induced or aggravated by interferon alpha; discontinue if persistent unexplained pulmonary infiltrates are noted. Gastrointestinal ischemia, ulcerative colitis and hemorrhage have been associated rarely with alpha interferons; some cases are severe and life-threatening. Ophthalmologic disorders (including retinal hemorrhages, cotton wool spots, and retinal artery or vein obstruction) have occurred in patients receiving alpha interferons; close monitoring is warranted.

Treatment should be discontinued in patients with worsening or persistently severe signs/symptoms of autoimmune, infectious, ischemic, or neuropsychiatric disorders (including depression and/or suicidal thoughts/behavior). Discontinue treatment if neutrophils <0.5 x 109/L or platelets <25 x 109/L. Due to differences in dosage, patients should not change brands of interferons. Injection solution contains benzyl alcohol; do not use in neonates or infants. Safety and efficacy in children <18 years of age have not been established.
DRUG INTERACTIONS — Inhibits CYP1A2 (weak)
Note: May exacerbate the toxicity of other agents with respect to CNS, myelotoxicity, or cardiotoxicity. See Lexi-Comp Online™ for details.

PREGNANCY RISK FACTOR — C

PREGNANCY IMPLICATIONS — Safety and efficacy for use during pregnancy have not been established. Interferon alpha has been shown to decrease serum estradiol and progesterone levels in humans. Menstrual irregularities and abortion have been reported in animals. Effective contraception is recommended during treatment.

LACTATION — Enters breast milk/contraindicated

BREAST-FEEDING CONSIDERATIONS — Women with hepatitis C should be instructed that there is a theoretical risk the virus may be transmitted in breast milk. HIV-infected mothers are discouraged from breast-feeding to decrease potential transmission of HIV.

PATIENT EDUCATION — Use as directed; do not change dosage or schedule of administration without consulting prescriber. Maintain adequate hydration (2-3 L/day of fluids unless instructed to restrict fluid intake). You may experience flu-like syndrome (acetaminophen may help); this syndrome subsides after several weeks of continuous dosing, but usually recurs during each cycle of intermittent therapy. You may also experience nausea, vomiting, dry mouth, or metallic taste (frequent small meals, frequent mouth care, sucking lozenges, or chewing gum may help); drowsiness, dizziness, agitation, abnormal thinking (use caution when driving or engaging in tasks requiring alertness until response to drug is known). Inform prescriber immediately if you feel depressed or have any thoughts of suicide. Report unusual bruising or bleeding; persistent abdominal disturbances; unusual fatigue; muscle pain or tremors; chest pain or palpitation; swelling of extremities or unusual weight gain; difficulty breathing; pain, swelling, or redness at injection site; or other unusual symptoms.

REFERENCES

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