INTERFERON THERAPY
ACTIMMUNE® (interferon gamma-1b) / ALFERON® N (interferon alfa-n3) / INFERGEN® (interferon alfacon-a) / INTRON® A (interferon alfa-2b)

CLINICAL RATIONALE

The immune system consists of different cells that protect the body against bacteria, fungi, tumors, viruses and other “foreign invaders”. Interferons are proteins produced by the body in response to infection. Interferons are chemical messengers that send signals to attack invading pathogens. Interferons may kill a virus directly, prevent the reproduction of a virus, or boost the body’s defense mechanism against a virus.

Three natural classes of interferons produced by the body are alpha, beta and gamma. Interferon alpha and beta are produced by the infection fighting cells in the blood and are important in antiviral activity. Interferon gamma is produced by activated T-cells and involved in modulating immune and inflammatory responses.

Commercially-produced, also known as genetically engineered, interferons are drugs used to mimic the activity of naturally-occurring interferons. Several types of interferon and pegylated interferon are available for human use. Pegylated interferons include one or more chains of polyethylene glycol (PEG) attached to the interferon. PEG acts as a protective barrier around the interferon. The benefit of pegylation is to clear the drug more slowly from the body, permitting less frequently dosing.

Common adverse effects of interferon therapy include the following: nausea, vomiting, diarrhea, loss of appetite, fatigue, fever, headache, muscle or joint aches, dizziness, difficulty sleeping, malaise, rash, and injection site redness or tenderness.

Other concerns with interferon therapy are adverse CNS effects, including depression and suicidal behavior, including suicidal ideation, suicidal attempts, and completed suicides. Patients with preexisting psychiatric conditions, especially depression, or a history of severe psychiatric disorder should not be treated with interferon. Liver toxicity, including fatal hepatotoxicity has been observed in interferon treated patients. Any patient developing liver function abnormalities during treatment should be monitored closely and if appropriate, treatment should be discontinued.

Adverse pulmonary effects: Pulmonary infiltrates, pneumonitis and pneumonia, including fatality, have been observed in interferon treated patients. The cause is not yet known. Any patient developing fever, cough, dyspnea, or other respiratory symptoms should have a chest X-ray taken. If the chest X-ray shows pulmonary infiltrates or there is evidence of pulmonary function impairment, the patient should be closely monitored, and, if appropriate, interferon treatment should be discontinued.

Autoimmune disease: Rare cases of autoimmune disease, including thrombocytopenia, vasculitis, Raynaud's phenomenon, rheumatoid arthritis, lupus erythematosus, and rhabdomyolysis have been observed in patients treated with interferon. Any patient developing an autoimmune disorder during treatment should be closely monitored and, if appropriate, treatment should be discontinued.

Prior approval is required to assure the drug is used only for conditions in which it has been demonstrated to be safe and effective.
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References
5. Lexicomp Accessed January 5, 2011