

FDA Approves Schering's Peg-Intron

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On January 22, Schering-Plough announced that the U.S. Food and Drug Administration (FDA) has approved their version of a pegylated interferon as a once-weekly monotherapy for the treatment of chronic hepatitis C. Schering's Peg-Intron becomes the first pegylated interferon approved for in the U. S. and is expected to be available to patients nationwide in early February 2001.

Pegylated interferon is interferon linked to a polyethylene glycol (peg) molecule designed to allow interferon's anti-viral abilities to last over a longer time period, and allowing a patient to inject this treatment once weekly instead of the thrice-weekly injections used with regular interferons. A once-weekly dose will allow patients to better tolerate the side effects of interferon therapy.

The Peg-Intron regiment approved in January is injected once weekly for a year by the patient, on the same day each week. Preliminary studies also show that pegylated interferons in combination with ribavirin have a greater success than the current standard "combo therapy" of regular interferon and ribavirin, the FDA has not yet approved pegylated interferon and ribavirin as a combination therapy.

The safety and efficacy of Peg-Intron has been demonstrated in a randomized, controlled clinical studies involving 1,219 adult patients with chronic hepatitis C who were not previously treated with alpha interferon. Patients were treated for 48 weeks. In the study, patients receiving Peg-Intron achieved a 24 percent treatment response rate of sustained virologic response and normal liver enzymes compared to a 12 percent treatment response rate in patients receiving regular interferon only.

The side effects associated with Peg-Intron were "flu-like" symptoms, which occurred in approximately 50 percent of patients; injection site irritation or inflammation, seen in 47 percent of patients; and depression, seen in 29 percent of patients.

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