Generic Name:
Peginterferon alfa-2a, ribavirin
Trade Name:
Pegasys, Copegus
Company:
Genentech
Notes:

FDA approved the combination treatment of peginterferon alfa-2a and ribavirin for treatment of pediatric patients 5 years and older with chronic hepatitis C infection who have compensated liver disease and no prior history of interferon therapy. The recommended dose of peginterferon alfa-2a for pediatric patients is 180 mcg per 1.73 m^2 of BSA, given once weekly, to a maximum dose of 180 mcg, for 24 weeks for patients with genotypes 2 or 3 or for 48 weeks for those with other genotypes. It must always be given in combination with ribavirin, which is dosed based on the patients? weight.

Approval was based on data from 114 patients ages 5 through 17 years who had chronic hepatitis C and were previously untreated. Patients were randomized to peginterferon alfa-2a and ribavirin (n = 55) or peginterferon alfa-2a monotherapy (n = 59). Combination treatment resulted in significantly higher sustained virological responses (53%) compared with monotherapy (20%).

An adverse event observed in this patient population with combination therapy was a delay in weight and height increases after 48 weeks of therapy compared with baseline. However, at the end of 2 years follow-up after treatment, most patients returned to baseline normative growth curve percentiles for height and weight. Other common adverse events were similar to those observed in adults (i.e., fatigue/asthenia, pyrexia, myalgia, headache).

This combination regimen was originally approved in adults with chronic hepatitis C infections and is also approved for adults with chronic hepatitis C coinfected with HIV.

Medication Monitor Categories:
Supplemental Approvals
Use:

Treatment of chronic hepatitis C infection in pediatrics