

Pegasys[®] (peginterferon alfa-2a) – Expanded indication

- On October 13, 2017, the [FDA approved](#) Hoffman-LaRoche's [Pegasys \(peginterferon alfa-2a\)](#), for the treatment of HBeAg-positive chronic hepatitis B (CHB) in non-cirrhotic pediatric patients 3 years of age and older with evidence of viral replication and elevations in serum alanine aminotransferase.
 - Previously, Pegasys was indicated for the treatment of adult patients with HBeAg-positive and HBeAg-negative CHB infection who have compensated liver disease and evidence of viral replication and liver inflammation.
- Pegasys is also indicated for the treatment of chronic hepatitis C (CHC) infection in the following:
 - Adult patients in combination therapy with other hepatitis C virus (HCV) antiviral drugs with compensated liver disease. Pegasys monotherapy is indicated only if patient has contraindication or significant intolerance to other HCV drugs. For information about the safe and effective use of other HCV antiviral drugs to be used in combination with Pegasys, refer to their prescribing information.
 - Pediatric patients in combination with [ribavirin](#) for patients 5 years of age and older with compensated liver disease.
 - Pegasys alone or in combination with ribavirin without additional HCV antiviral drugs is not recommended for treatment of patients with CHC who previously failed therapy with an interferon-alfa.
 - Pegasys is not recommended for treatment of patients with CHC who have had solid organ transplantation.
- The expanded indication was approved based on a study enrolling 151 patients ages 3 - < 18 years of age who had HBeAg-positive CHB. Patients received Pegasys or no treatment for 48 weeks.
 - HBeAg seroconversion occurred in 26% of Pegasys-treated patients vs. 6% of the untreated group (Odds ratio = 5.43; 95% CI: 1.54, 19.20).
- Pegasys carries a boxed warning for risk of serious disorders.
- The most common adverse reactions for Pegasys use in pediatric patients are similar to those seen in adults (> 40%): fatigue/asthenia, pyrexia, myalgia, and headache.
- The recommended dosage of Pegasys in pediatric patients for HBeAg-positive CHB is 180 mcg/1.73 m² x BSA subcutaneously once weekly to a maximum dose of 180 mcg. The recommended duration of therapy is 48 weeks.
 - Consult Pegasys' drug label for dosage recommendations for all other indications.