

# Peginterferon alfa-2a (*Pegasys*)

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## Drug Summary

Peginterferon alfa-2a ([Figure 1](#)) and ([Figure 2](#)) and ([Figure 3](#)) played a role in the treatment of chronic hepatitis C prior to the availability of direct-acting antiviral agents. Peginterferon alfa-2a is no longer recommended for the treatment of hepatitis C due to relatively poor efficacy and high rate of adverse effects.

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## Adverse Effects

In most patients, peginterferon alfa-2a causes numerous problematic side effects. In clinical studies involving peginterferon alfa-2a, the following adverse effects were reported most often: headache, fatigue, and influenza-like symptoms, including myalgia, pyrexia, arthralgia, nausea, and anorexia. In addition, significant hematologic toxicity can occur due to peginterferon alfa-2a, including neutropenia and thrombocytopenia. Patients can develop ophthalmologic disorders and all patients should receive a baseline eye examination and should have a prompt eye examination if they develop ocular symptoms. Neuropsychiatric effects such as insomnia, depression, and irritability can also occur. Peginterferon alfa-2a may cause or aggravate life-threatening neuropsychiatric, autoimmune, ischemic, or infectious disorders. Further, the use of peginterferon in patients with cirrhosis can cause life-threatening hepatic decompensation. To report suspected adverse reactions, contact (1) Genetech at 1-888-835-2555 or (2) the FDA at 1-800-FDA-1088.

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## Class and Mechanism

Peginterferon alfa-2a consists of interferon alfa-2a covalently linked to a 40-kd branched polyethylene glycol (PEG). The biologic activity of peginterferon-alfa-2a derives from its interferon alfa-2a moiety, which impacts both adaptive and innate immune responses against hepatitis C virus. This alpha interferon binds to and activates human type 1 interferon receptors on hepatocytes which activates multiple intracellular signal transduction pathways, culminating in the expression of interferon-stimulated genes that produce an array of antiviral effects, such as blocking viral protein synthesis and inducing viral RNA mutagenesis. Compared with the native interferon alfa-2a, the peginterferon alfa-2a has sustained absorption, delayed clearance, and a prolonged half life.

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## Indications

Peginterferon alfa-2a is indicated, in combination with ribavirin, for the treatment of chronic hepatitis C (HCV) in patients 5 years and older with compensated liver disease, including patients with HCV and HIV coinfection (with a CD4 count greater than 100 cells/mm<sup>3</sup>). In addition, peginterferon alfa-2a is indicated in combination with ribavirin and an approved HCV NS3/4A protease inhibitor in adult patients with genotype 1 HCV infection. Use of peginterferon alfa-2a is contraindicated in patients with autoimmune hepatitis, hepatic decompensation in patients with cirrhosis, and in patients with a known hypersensitivity reaction to any form of alfa interferon.

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## Dosing

Peginterferon alfa-2a is available as a 180 mcg/1.0 ml vial for single use, a 180 mcg/0.5 ml prefilled syringe for single use ([Figure 2](#)), a 180 mcg/0.5 ml autoinjector for single use ([Figure 3](#)), and a 135 mcg/0.5 ml autoinjector for single use. In adults, the recommended dose of peginterferon alfa-2a is 180 mcg subcutaneously administered once weekly in the abdomen or thigh. The 180-mcg dose is the recommended initial starting dose, regardless of the patient's weight or HCV genotype. The dose of peginterferon alfa-2a may require modification as outlined below.

- **Leukopenia:** The dose of peginterferon alfa-2a should be reduced to 135 mcg in patients who have an absolute neutrophil count (ANC) that declines to less than 750 cells/mm<sup>3</sup>; if the ANC declines to less than 500 cells/mm<sup>3</sup>, discontinue peginterferon alfa-2a until the ANC rises to greater than 1000 cells/mm<sup>3</sup> and then restart at 90 mcg with close monitoring of the ANC.
- **Thrombocytopenia:** The dose of peginterferon alfa-2a should be reduced to 90 mcg in patients who have a decline in platelet count to a less than 50,000 cells/mm<sup>3</sup>; discontinue therapy if the platelet count declines to less than 25,000 cells/mm<sup>3</sup>.
- **Renal Insufficiency:** If the creatinine clearance is less than 30 mL/min or the patient is on hemodialysis, the dose of peginterferon alfa-2a should be reduced to 135 mcg and the patient should have close monitoring for any signs of medication toxicity. If toxicity (laboratory or clinical) develops, the dose of peginterferon alfa-2a can be reduced further to 90 mcg.
- **Increased Alanine Transaminase (ALT):** In patients who have persistent elevations in ALT levels above baseline, the recommendation is to have increased frequency of monitoring and reduce the dose of peginterferon alfa-2a to 135 mcg.
- **Depression:** the dose of peginterferon alfa-2a may need adjusting in patients who develop

depression. In general, mild depression does not require a dose adjustment, but does warrant close monitoring. For moderate depression, the dose of peginterferon alfa-2a should be reduced to 135 mcg (or 90 mcg in some instances), with close follow-up and consideration for psychiatric consultation. With severe depression, therapy should be discontinued and the patient should immediate psychiatric consultation should be obtained.

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## Cost and Medication Access

For information regarding coverage, reimbursement, and patient assistance for peginterferon alfa-2a (Pegasys), visit the [Access Solutions](#) website or call 1-888-941-3331. This is the same patient assistance program for the Genetech manufactured ribavirin (Copegus).

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## Key Drug Interactions

For complete information on peginterferon alfa-2a-related drug interactions, see the [Drug Interactions section in the Peginterferon alfa-2a \(Pegasys\) Prescribing Information](#).

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## Full Prescribing Information

[Peginterferon alfa-2a \(Pegasys\) Full Prescribing Information](#).

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## Figures

[Figure 1. Packaging - Peginterferon alfa-2a \(Pegasys\)](#)

Photo: Andrew Karpenko, University of Washington

[Figure 2. Single Use Syringe - Peginterferon alfa-2a \(Pegasys\)](#)

Photo: Andrew Karpenko, University of Washington

[Figure 3. 180 mcg/0.5 ml autoinjector - Peginterferon alfa-2a \(Pegasys\)](#)

Photo: Andrew Karpenko, University of Washington