

Peginterferon alfa-2b (*PegIntron*)

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Drug Summary

Peginterferon alfa-2b ([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-2b is no longer recommended for the treatment of hepatitis C due to relatively poor efficacy and high rate of adverse effects.

Adverse Effects

In most patients, peginterferon alfa-2b causes numerous problematic side effects. In clinical studies, the most common adverse reactions (reported in greater than 40%) were injection site inflammation/reaction, fatigue, headache, rigors, fevers, nausea, myalgia, and anxiety or emotional lability/irritability. 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 while on therapy. Neuropsychiatric effects such as insomnia, depression, and irritability can also occur. Peginterferon alfa-2b may cause or aggravate life-threatening neuropsychiatric, autoimmune, ischemic, or infectious disorders. Further, the use of peginterferon alfa-2b in patients with cirrhosis can cause life-threatening hepatic decompensation. To report suspected adverse reactions, contact (1) Schering Corporation, a subsidiary of Merck & Co., at 1-800-526-4099 or (2) the FDA at 1-800-FDA-1088.

Class and Mechanism

Peginterferon alfa-2b consists of interferon alfa-2b covalently linked to a 12-kd linear polyethylene glycol (PEG). The biologic activity of peginterferon-alfa-2b derives from its interferon alfa-2b 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-2b, the peginterferon alfa-2b has sustained absorption, delayed clearance, and a prolonged half life.

Indications

Peginterferon alfa-2b is indicated for the treatment of patients with chronic hepatitis C who have compensated liver disease.

- Peginterferon alfa-2b is indicated in combination with ribavirin and an approved HCV NS3/4A protease inhibitor for adult patients with genotype 1 infection.
- Peginterferon alfa-2b is indicated in combination with ribavirin for the treatment of HCV genotypes other than 1.
- Peginterferon alfa-2b is indicated in combination with ribavirin for the treatment of HCV genotype 1 where use of an HCV NS3/4A protease inhibitor is not warranted because of contraindications, inability to tolerate, or other clinical factors.

Dosing

Peginterferon alfa-2b is available as a single use 1.25 mL vial, *REDIPEN* single-use pre-filled pen, and *Selectdose* single-use pre-filled pen, with all available in the following strengths: 50 mcg/0.5 mL, 80 mcg/0.5 mL, 120 mcg/0.5 mL, or 150 mcg/0.5 mL in a single use vial. In adults, the recommended dose of peginterferon alfa-2b is 1.5 mcg/kg administered subcutaneously once weekly. Patients should be instructed to discharge the unused portion of peginterferon alfa-2b in the vial or pre-filled syringe. The dose of peginterferon alfa-2b may require modification due to development of laboratory abnormalities, such as leukopenia, anemia, or thrombocytopenia; in this situation, the dose reductions with adult patients taking a regimen that includes peginterferon alfa-2b and ribavirin is a two-step process with the first reduction of peginterferon alfa-2b to 1.0 mcg/kg/week and the second, if needed, to 0.5 mcg/kg/week.

- **Leukopenia:** The dose of peginterferon alfa-2b should be reduced in patients who have a white blood cell (WBC) count in the range of 1000 to less than 1550 cells/mm³ or an absolute neutrophil count (ANC) in the range of 500 to less than 750 cells/mm³; therapy should be discontinued if the WBC declines to less than 1000 cells/mm³ or the ANC declines to less than 500 cells/mm³.
- **Thrombocytopenia:** The dose of peginterferon alfa-2b should be reduced in patients who have a platelet count in the range of 25,000 to less than 50,000 cells/mm³; therapy should be discontinued if the platelet count declines to less than 25,000 cells/mm³.
- **Renal Insufficiency:** If the patient has moderate renal insufficiency (creatinine clearance 30 to 50 mL/min), the dose of peginterferon alfa-2b should be reduced by 25% (from the standard dose of 1.5 mcg/kg once weekly to 1.125 mcg/kg once weekly). For patients with severe renal insufficiency (creatinine clearance 10 to 29 mL/min), including those on hemodialysis, the recommended dose of

peginterferon alfa-2b should be reduced by 50% (from 1.5 mcg/kg once weekly to 0.75 mcg/kg once weekly). In addition, peginterferon alfa-2b should be discontinued if renal dysfunction develops during therapy.

- Depression: the dose of peginterferon alfa-2b 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, reduce the dose of peginterferon alfa-2b, with close follow-up, and consider psychiatric consultation. With severe depression, therapy should be discontinued, and the person should immediate psychiatric consultation should be obtained.

Key Drug Interactions

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

Full Prescribing Information

[Peginterferon alfa-2b \(PegIntron\) Full Prescribing Information](#)

Figures

[Figure 1. Packaging - Peginterferon alfa-2b \(PegIntron\)](#)

Photo: Andrew Karpenko, University of Washington

[Figure 2. RediPen® - Peginterferon alfa-2b \(PegIntron\)](#)

Photo: Andrew Karpenko, University of Washington

[Figure 3. RediPen® Dose Selector - Peginterferon alfa-2b \(PegIntron\)](#)

Photo: Andrew Karpenko, University of Washington