Pegferon®

Peg interferon alfa 2a BP

Presentation

Pegferon® 180 g injection: each pre-filled syringe contains 0.5 ml sterile solution of peginterferon alfa 2a BP 180 g
Pegferon® 135 g injection: each pre-filled syringe contains 0.5 ml sterile solution of peginterferon alfa 2a BP 135 g

Description

Peginterferon alfa-2a, is a covalent conjugate of recombinant alfa-2a interferon with a single branched bis-monomethoxy polyethylene glycol (Pegferon®) chain. The Pegferon® moiety is linked at a single site to the interferon alfa moiety via a stable amide bond to lysine. Peginterferon alfa-2a has an approximate molecular weight of 60,000 daltons. Interferon alfa-2a is produced using recombinant DNA technology in which a cloned human leukocyte interferon gene is inserted into and expressed in Escherichia coli.

Indications and Usage

Chronic Hepatitis C
Peginterferon alfa-2a, alone or in combination with Ribavirin, is indicated for the treatment of aadults with chronic hepatitis C (CHC) virus infection who have compensated liver disease and have not been previously treated with interferon alpha.
Chronic Hepatitis B
peginterferon alfa-2a, is indicated for the treatment of adult patients with HBeAg positive and HBeAg negative chronic hepatitis B infection who have compensated liver disease and evidence of viral replication and liver inflammation.

Dosage and Administration

Chronic Hepatitis C: The recommended dose of Pegferon® for chronic hepatitis C is 180 mcg once weekly for 48 weeks by subcutaneous administration on abdomen or thigh
Chronic Hepatitis B: The recommended dose of Pegferon® for chronic hepatitis B is 180 mcg once weekly for 48 weeks by subcutaneous administration on abdomen or thigh

Pegferon® Dose Modification Guidelines

Laboratory Values	Recommended Dose	Discontinue
ANC >750 cells/mm^3	Maintain 180 g	ANC <500 /mm^3
ANC <750 cells/mm^3	Reduces to 135 g	
Platelet >50,000 cells/mm^3	Maintain 180 g	Platelet <25,000 cells/mm^3
Platelet <50,000 cells/mm^3	Reduces to 90 g	

Adverse Reactions

Depression, suicide, relapses of drug abuse/overdose, and bacterial infections
Flu-like Symptoms and Signs:Fatigue/Asthenia, Pyrexia, Rigors, Pain
Gastrointestinal: Nausea/Vomiting, Diarrhea, Abdominal pain, Dry mouth,Dyspepsia
Metabolic and Nutritional: Anorexia
Musculoskeletal: Myalgia, Arthralgia, Back pain
Neurological: Headache, Dizziness, Memory impairment
Psychiatric: Irritability/Anxiety/Nervousness, Insomnia,Depression
Injection Site Reactions: Skin problem, Hair Loss.
Endocrine Disorders: Hypothyroidism

Contraindications

- Known hypersensitivity reactions such as urticaria, angioedema, bronchoconstriction and anaphylaxis to alpha interferons or any component of the product
- Autoimmune hepatitis
- Hepatic decompensation in cirrhotic patients before or during treatment
- Hepatic decompensation with Child-Pugh score greater than or equal to 6 in cirrhotic CHC patients coinfected with HIV during or before treatment
- Neonates or infants

Precautions

- Patients who have failed alpha interferon treatment with or without ribavirin
- Liver and other organ transplant recipients
- Hepatitis B patients co-infected with HCV or HIV
- Hepatitis C patients co-infected with HBV or HIV with a CD4+ cell count < 100 cells/ul
- Caution should be exercised in initiating treatments in any patients with baseline risk of severe anemia

Pregnancy & Lactation

Pregnancy Category C: Peginterferon alfa 2a Monotherapy
Pegferon® has not been studied for its teratogenic effect. There are no adequate and well-controlled studies of Pegferon® in pregnant women. Pegferon® is recommended for use in women of childbearing potential only when they are using effective contraception during therapy.
Pregnancy Category X: Use with Ribavirin
Significant teratogenic and/or embryocidal effects have been demonstrated in all animal species exposed to ribavirin. Combination therapy is contraindicated in women who are pregnant and in the male partners of women who are pregnant
Nursing Mothers
The effect of orally ingested peginterferon or ribavirin from breast milk on the nursing infant has not been evaluated. Because of the potential for adverse reactions from the drugs in nursing infants, a decision must be made whether to discontinue nursing or discontinue peginterferon and ribavirin treatment.
Pediatric Use
The safety and effectiveness of Pegferon®, alone or in combination with Ribavirin in patients below the age of 5 years have not been established.

Drug Interactions

- Drugs metabolized by CYP1A2: monitor for increased serum levels of theophylline and adjust dose accordingly
- Methadone: monitor for signs and symptoms of methadone toxicity
- Nucleoside analogues: closely monitor for toxicities. Reduce or discontinue the dose of Peginterfeon or Ribavirin or both should the events worsen
- Zidovudine: monitor for worsening neutropenia and/or anemia with peginterferon alfa / rivabirin Azathioprine

Over dosage

There is limited experience with overdosage. There were no serious reactions attributed to overdosages. There is no specific antidote for Pegferon®. Hemodialysis and peritoneal dialysis are not effective.

Commercial pack

Pegferon® 180 g prefilled syringe injection: Each box contains 1 pre-filled syringe containing 0.5 ml sterile solution of peginterferon alfa 2a BP 180 g
Pegferon® 135 g prefilled syringe injection: Each box contains 1 pre-filled syringe containing 0.5 ml sterile solution of peginterferon alfa 2a BP 135 g

Storage

Peginterferon should be stored in a refrigerator at 2 ^{0}C to 8 ^{0}C. Do not freeze. Protect from light.

Medicine keep out of reach of children

Healthcare

Manufactured by
Healthcare Pharmaceuticals Ltd.
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HP 52234