HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PEGASYS safely and effectively. See full prescribing information for PEGASYS.

PEGASYS® (peginterferon alfa-2a) injection, for subcutaneous use
Initial U.S. Approval: 2002

WARNING: RISK OF SERIOUS DISORDERS
See full prescribing information for complete boxed warning.

Risk of Serious Disorders
- **May cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Monitor closely and withdraw therapy with persistently severe or worsening signs or symptoms of the above disorders (5)**

----------RECENT MAJOR CHANGES----------
Warnings and Precautions,
Impact on Growth in Pediatric Patients (5.15) 12/2023

---------- INDICATIONS AND USAGE----------
PEGASYS is an inducer of the innate immune response indicated for the treatment of
Chronic Hepatitis C (CHC) (1.1)
- Adult Patients: In combination therapy with other hepatitis C virus drugs for adults with compensated liver disease. PEGASYS monotherapy is indicated only if patient has contraindication or significant intolerance to other HCV drugs.
- Pediatric Patients: In combination with ribavirin for pediatric patients 5 years of age and older with compensated liver disease

Chronic Hepatitis B (CHB) (1.2)
- Adult Patients: Treatment of adults with HBeAg-positive and HBeAg-negative chronic hepatitis B (CHB) infection who have compensated liver disease and evidence of viral replication and liver inflammation
- Pediatric Patients: Treatment of non-cirrhotic pediatric patients 3 years of age and older with HBeAg-positive CHB and evidence of viral replication and elevations in serum alanine aminotransferase (ALT)

----------DOSAGE AND ADMINISTRATION----------
- PEGASYS is administered by subcutaneous injection (2)
- In adult patients with CHC, PEGASYS is dosed as 180 mcg per week and the duration of treatment depends on indication, genotype, and whether it is administered with other HCV antiviral drugs (2.2).
- In adult patients with CHB, PEGASYS is dosed as 180 mcg per week for 48 weeks (2.4).
- In pediatric patients with CHC, PEGASYS is dosed as 180 mcg/1.73 m^2 x BSA per week, in combination with ribavirin, and the duration of treatment depends on genotype (2.3)
- In pediatric patients with CHB, PEGASYS is dosed as 180 mcg/1.73 m^2 x BSA per week for 48 weeks (2.5):
- Dosage modification is recommended in patients experiencing certain laboratory abnormalities, adverse reactions or renal impairment (2.6, 12.3)

---------- DOSAGE FORMS AND STRENGTHS----------
Injection:
- 180 mcg/mL solution in a single-dose vial (3)
- 180 mcg/0.5 mL solution in a single-dose prefilled syringe (3)

---------- CONTRAINDICATIONS ----------
- Autoimmune hepatitis (4)
- Hepatic decompensation in patients with cirrhosis (4)
- Use in neonates/infants (4)
- Known hypersensitivity reactions such as urticaria, angioedema, bronchoconstriction and anaphylaxis to alpha interferons or any component of the product (4)

Additional contraindications for use with other HCV antiviral drugs:
- When used in combination with other HCV antiviral drugs, all contraindications also apply to PEGASYS combination therapy (4)
- Ribavirin is contraindicated in pregnant women and men whose female partners are pregnant (4, 8.1)

---------- WARNINGS AND PRECAUTIONS ----------
Use with Ribavirin
- Birth defects and fetal death: patients must have a negative pregnancy test prior to therapy, use 2 forms of effective contraception, and have monthly pregnancy tests (5.1)

PEGASYS Clinically Significant Adverse Reactions or Risks
Patients exhibiting the following events should be closely monitored and may require dose reduction or discontinuation of therapy:
- Neuropsychiatric reactions (5.2)
- Cardiovascular disorders (5.3)
- Bone marrow suppression (5.4)
- Autoimmune and endocrine disorders (including thyroid disorders; hyperglycemia) (5.5, 5.6)
- Ophthalmologic disorders (5.7)
- Cerebrovascular disorders (5.8)
- Hepatic decompensation in cirrhotic patients. Exacerbation of hepatitis during hepatitis B treatment (5.9)
- Pulmonary disorders (5.10)
- Infections (bacterial, viral, fungal) (5.11)
- Colitis and pancreatitis (5.12, 5.13)
- Hypersensitivity and serious skin reactions including Stevens-Johnson syndrome (5.14)
- Growth impairment with combination therapy in pediatric patients (5.15)
- Peripheral neuropathy when used in combination with telbivudine (5.16)

---------- ADVERSE REACTIONS ----------
- Adult subjects: The most common adverse reactions (incidence greater than 40%) are fatigue/asthenia, pyrexia, myalgia, and headache (6.1)
- Pediatric subjects: The most common adverse reactions are similar to those seen in adults (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact pharma& agent at 1-888-814-7734 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---------- DRUG INTERACTIONS----------
- Drugs metabolized by CYP1A2: monitor for increased serum levels of theophylline and adjust dose accordingly (7.2)
- Methadone: monitor for signs and symptoms of methadone toxicity (7.3)
- Nucleoside analogues: closely monitor for toxicities. Reduce or discontinue the dose of PEGASYS or ribavirin or both should the events worsen (7.4)
- Zidovudine: monitor for worsening neutropenia and/or anemia with PEGASYS and/or ribavirin (7.4)

---------- USE IN SPECIFIC POPULATIONS ----------
- Pediatric patients: Safety and efficacy in CHC pediatric patients less than 5 years old and CHB pediatric patients less than 3 years old have not been established (8.4)
- Geriatric patients: Neuropsychiatric, cardiac, and systemic (flu-like) adverse reactions may be more severe (8.5)
- Patients with hepatic impairment: Clinical status and hepatic function should be closely monitored and treatment should be immediately discontinued if decompensation occurs (8.6)
- Patients with renal impairment: PEGASYS dose should be reduced in patients with creatinine clearance less than 30 mL/min (2.6, 8.7)
- CHB: Safety and efficacy have not been established in hepatitis B patients coinfected with HCV or HIV (8.9)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved Medication Guide.

Revised: 12/2023