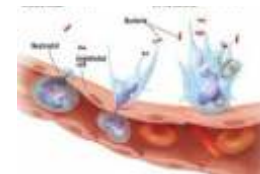
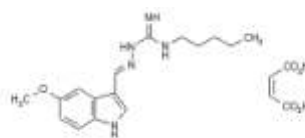


Rx PEGINTERFERON ALFA-2A

(Biological response modifier 180-mcg/ml vial)



Pegasys

Pharmacologic class: Interferon

Therapeutic class: Biological response modifier

Pregnancy risk category C

FDA Boxed Warning

- Drug may cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Monitor patient closely with periodic clinical and laboratory evaluations. Withdraw drug in patients who have persistently severe or worsening signs or symptoms of these conditions. In most cases, these disorders resolve once therapy ends.

- Concurrent use with ribavirin may cause birth defects or fetal death. Use extreme care to avoid pregnancy in female patients and female partners of male patients.

Action

Unclear. Thought to bind to specific cell-surface receptors, suppressing cell proliferation and viral replication. Also increases effector protein levels and reduces white blood cell (WBC) and platelet counts.

Availability

Injection: 180-mcg/ml vial

Indications and dosages

Chronic hepatitis C virus infection

Adults: 180 mcg subcutaneously q week for 48 weeks. If poorly tolerated, reduce to 135 mcg weekly; some patients may need reduction to 90 mcg.
Dosage adjustment

- Neutrophil count less than 750 cells/mm³ or platelet count less than 50,000 cells/mm³
- Hepatic disease
- End-stage renal disease requiring dialysis
- Serious adverse reactions

Off-label uses

- Renal cell carcinoma

Contraindications

- Hypersensitivity to drug
- Autoimmune hepatitis
- Decompensated hepatic disease
- Infants and neonates (due to benzyl alcohol content)

Precautions

Use cautiously in:

- thyroid disorders; bone marrow depression; hepatic, renal, or cardiac disease; pancreatitis; autoimmune disorders; pulmonary disorders; colitis; ophthalmic disorders; depression
- elderly patients
- pregnant or breastfeeding patients
- children younger than age 18.

Administration

- Keep refrigerated. Before giving, roll vial between palms for 1 minute to warm; don't shake. Protect solution from light.
- Don't use if solution is cloudy or contains visible particles.
- Administer undiluted in abdomen or thigh by subcutaneous injection.
- Know that drug may be used alone or with ribavirin.

Route Onset Peak Duration

Subcut. Gradual 72-96 hr Unknown

Adverse reactions

CNS: dizziness, vertigo, insomnia, fatigue, rigors, poor memory and concentration, asthenia, depression, irritability, anxiety, peripheral neuropathy, mood changes, suicidal ideation

CV: hypertension, chest pain, supraventricular arrhythmias, myocardial infarction

EENT: vision loss, blurred vision, retinal artery or vein thrombosis, retinal hemorrhage, optic neuritis, retinopathy, papilledema

GI: nausea, vomiting, diarrhea, abdominal pain, dry mouth, anorexia, GI tract bleeding, ulcerative and hemorrhagic colitis, pancreatitis

Hematologic: anemia, leukopenia, thrombocytopenia, neutropenia

Metabolic: diabetes mellitus, aggravated hypothyroidism or hyperthyroidism

Musculoskeletal: myalgia, back pain, joint pain

Respiratory: pneumonia, interstitial pneumonitis, bronchoconstriction, respiratory failure

Skin: alopecia, pruritus, diaphoresis, rash, dermatitis, dry skin, eczema

Other: weight loss, flulike symptoms, injection-site reaction, pain, autoimmune phenomena, severe and possibly fatal bacterial infections, severe hypersensitivity reactions including angioedema and anaphylaxis

Interactions

Drug-drug. Theophylline: increased theophylline blood level

Drug-diagnostic tests. Absolute neutrophil count, hematocrit, hemoglobin, platelets, **WBCs:** decreased values

Alanine aminotransferase: transient increase

Glucose, thyroid function tests: decreased or increased levels

Triglycerides: increased levels

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



Taj Group of Companies ^{INDIA}

Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91,

(0)22 - 26374592/93 91 - (0)22 - 30601000,

Fax : 91-(0)22-26341274

Revised November 2010