Journal Academy Formulary (JACF)

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Drug Review: Eflapegrastim

Registrations: It had been registered in the following countries United States of America (USA), United Kingdom (U.K.), Canada, and Saudi Arabia (S.A.)
Trade name (USA); ROLVEDON
Registration number (S.A.); Not Available.
Insurance Drug Formulary (S.A.); Not covered (29.1.2023).
General Information:
Registered Company: Spectrum Pharmaceuticals.
Regulatory Status: R.X.
Mechanism of Action:
A recombinant human granulocyte growth factor activates signaling pathways that affect cell differentiation, proliferation, migration, and survival by binding to G-CSF receptors on myeloid progenitor cells and neutrophils.

Indication
In patients with non-myeloid malignancies taking myelosuppressive anti-cancer medications, a clinically significant incidence of febrile neutropenia is associated with myelosuppressive anti-cancer drugs; Prophylaxis.
Route of Administration: Sub-Q.
Dosage Forms: Subcutaneous Solution: 13.2 MG/0.6 ML.
Dosing/Administration:
13.2 mg sub Q administered once per chemotherapy cycle as a single injection approximately 24 hr after cytotoxic chemotherapy. Do not administer within the period from 14 days before to 24 hr after administration of cytotoxic.
Chemotherapy; do not administer within the period from 14 days before to 24 hr after administration of cytotoxic chemotherapy.
Dose: Dose in Renal/Hepatic failure: No dosage adjustment is needed.
Geriatric Dose: No dosage adjustment is needed.
Adjustment required in Specific population: No dosage adjustment is needed.
Indicated for pediatrics: Safety and effectiveness not established in pediatric patients.

Pharmacokinetic:

Absorption
- T_{max}, sub Q: 25 hr.

Distribution
- Vd: 1.44 L.

Metabolism
- Metabolism: Endogenous degradation.

Excretion
- Renal excretion: Not detected.

Elimination Half-Life: 36.4 hr.

Safety:
Common Adverse Reactions (%):
Gastrointestinal: Diarrhea (40%), Nausea (52%).
Hematologic: Anemia (25%).
Musculoskeletal: Arthralgia (21%), Backache (20%), Bone pain (38%), Myalgia (22%).
Neurologic: Headache (29%).
Other: Fever (28%).

Severe/rare adverse Reactions (%):
Cardiovascular: Aortitis, Capillary leak syndrome.
Hematologic: Acute myeloid leukemia, Leukocytosis, Myelodysplastic syndrome, Rupture of the spleen, Sickle cell anemia with crisis.
Immunologic: Anaphylaxis, Hypersensitivity reaction.
Respiratory: Acute respiratory distress syndrome.

Drug Interactions:
Interact with drugs such:
- abemaciclib.
- cisplatin.
- dinutuximab.
- lithium.
- oxaliplatin.
- rituximab.
- vincristine.

Contraindications / Precautions

Contraindications:
History of severe allergic reactions to eflapegrastim, pegfilgrastim, or filgrastim product.

Precautions
- Cardiovascular: Capillary leak syndrome (hypotension, hypoalbuminemia, edema, and hemoconcentration) has been reported with rhG-CSF products; frequency and severity may vary. The condition may be life-threatening if treatment is delayed; monitoring is required, and treatment may be necessary.
- Cardiovascular: Aortitis (abdominal pain, fever, back pain, malaise, and increased inflammatory markers Such: C-reactive protein and WBC count; it may occur as early as the first week after initiation. Consider aortitis in patients with signs and symptoms without known etiology and discontinue use if suspected.
- Hematologic: Splenic Rupture, including fatalities, can occur; monitoring recommended.
- Hematologic: Patients with sickle cell disease can experience severe and even fatal sickle cell crises.; discontinuation may be necessary.

Monitoring Requirements:
- A decrease in the number of days with severe neutropenia may indicate efficacy.
- CBC: During therapy, including differential.
- Acute respiratory distress syndrome Signs and symptoms.
- Signs and symptoms of an enlarged spleen or splenic Rupture.
- Signs and symptoms of myelodysplastic syndrome and acute myeloid leukemia: In patients with lung cancer or breast treated with recombinant human granulocyte colony-stimulating factors plus chemotherapy and radiotherapy.

Sound-Alikes/ Look-Alikes: Not available.
High Alert: Not available.
Boxed warnings or alerts issue: Not available.
Toxicity if antidote required: Not available.
Storage if there is a special condition:

Solution

Store in original carton refrigerated between 2-8°C protect from light.
Do not shake, freeze, or drop on a hard surface.
Discard syringes stored at room temperature for over 12 hr or if frozen.

Patient counseling

1. Use the medication as recommended.
2. Take this medication every day at the same time.
3. Adverse effects are possible: Fatigue, Nausea, diarrhea, bone pain, headache, anemia, rash, myalgia, arthralgia, and back pain.

Cost Analysis:

Drugs	Drug classes	Approval Indication	Dose	Cost (American Dollar)	Insurance drug formulary(SCHI)
Eflapegrastim	Blood Modifier Agent	In patients with non-myeloid malignancies taking myelosuppressive anti-cancer medications, a clinically significant incidence of febrile neutropenia is associated with myelosuppressive anti-cancer drugs; Prophylaxis.	13.2 mg sub Q administered once per chemotherapy cycle as a single injection approximately 24 hr after cytotoxic chemotherapy; do not administer within the period from 14 days before to 24 hr after administration of cytotoxic chemotherapy.	Subcutaneous solution (xnst 13.2 mg/0.6 mL) is around $4,748 for a supply of 0.6 milliliters	Not Covered
Pegfilgrastim	Blood Modifier Agent	Incidence of febrile neutropenia in patients with non-myeloid malignancies taking myelosuppressive anti-cancer medications; Prophylaxis Hematopoietic subsyndrome of acute radiation syndrome	-(Single-dose prefilled syringe or on-body injector) 6 mg sub Q once per chemotherapy cycle; do not administer between 14 days prior to and 24 hr after the administration of chemotherapy (FDA dosage) Harvesting of peripheral blood stem cells before the autologous stem-cell transplantation -18 mg sub Q as a single dose 24 hr after myeloablative chemotherapy (off-label dosage).	$6,417.99* per dose	Covered

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