

Embardia™

Darbepoetin alfa Injection

Presentation

Embardia™ 25 mcg Injection: Each pre-filled syringe contains Darbepoetin alfa INN 25 mcg in 0.42 ml solution for injection.

Embardia™ 40 mcg Injection: Each pre-filled syringe contains Darbepoetin alfa INN 40 mcg in 0.40 ml solution for injection.

Embardia™ 60 mcg Injection: Each pre-filled syringe contains Darbepoetin alfa INN 60 mcg in 0.30 ml solution for injection.

Description

Darbepoetin alfa is a re-engineered form of erythropoietin containing 5 amino acid changes. It has a 3-fold longer serum half-life compared to erythropoietin alpha and erythropoietin beta. It stimulates erythropoiesis by the same mechanism as rHuEpo (binding and activating the Epo receptor) and is used to treat anemia.

Indication and Usage

Darbepoetin alfa is an erythropoiesis-stimulating agent (ESA) indicated for the treatment of anemia due to:

- Chronic Kidney Disease (CKD) in patients on dialysis and patients not on dialysis
- The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned Chemotherapy

Dosage administration

Recommended starting dose for CKD patients on dialysis:

- 0.45 mcg/kg intravenously or subcutaneously weekly, or
- 0.75 mcg/kg intravenously or subcutaneously every 2 weeks
- Intravenous route is recommended for patients on hemodialysis

Recommended starting dose for patients with CKD not on dialysis:

- 0.45 mcg/kg intravenously or subcutaneously at 4-week intervals

Recommended starting dose for cancer patients on chemotherapy:

- 2.25 mcg/kg subcutaneously weekly, or
- 500 mcg subcutaneously every 3 weeks

Side-effects

Patients with CKD: Adverse reactions in ≥ 10% of Darbepoetin alfa patients in clinical studies were hypertension, dyspnea, peripheral edema, cough, and procedural hypotension.

Cancer Patients Receiving Chemotherapy: Adverse reactions in ≥ 1% of Darbepoetin alfa-treated patients in clinical studies were abdominal pain, edema, and thrombovascular events.

Contraindications

Darbepoetin alfa is contraindicated in the following patients:

- Uncontrolled hypertension
- Pure red cell aplasia (PRCA) that begins after treatment with Darbepoetin alfa or other erythropoietin protein drugs
- Serious allergic reactions to Darbepoetin alfa

Precaution

- **Increased Mortality, Myocardial Infarction, Stroke, and Thromboembolism:** Using Darbepoetin alfa to target a hemoglobin level of greater than 11 g/dL increases the risk of serious adverse cardiovascular reactions and has not been shown to provide additional benefit. Use caution in patients with coexistent cardiovascular disease and stroke
- **Increased mortality and/or increased risk of tumor progression or recurrence in patients with cancer**
- **Hypertension:** Control hypertension prior to initiating and during treatment with Darbepoetin alfa
- **Seizures:** Darbepoetin alfa increases the risk for seizures in patients with CKD. Increase monitoring of these patients for changes in seizure frequency or premonitory symptoms
- **PRCA:** If severe anemia and low reticulocyte count develop during Darbepoetin alfa treatment, withhold Darbepoetin alfa and evaluate for PRCA

Use in specific population

Pregnancy: Based on animal data, may cause fetal harm.

Nursing Mothers: Exercise caution when Darbepoetin alfa is administered to a nursing woman.

Pediatric Use: Safety and efficacy not established in the initial treatment of anemic patients with CKD, in the transition from another erythropoietin in patients with CKD who are less than 1 year of age, or in pediatric patients with cancer.

Drug interaction

No formal drug interaction studies have been conducted with Darbepoetin alfa.

Overdosage

Darbepoetin alfa can cause hemoglobin levels above the desired level, which should be managed with discontinuation or reduction of Darbepoetin alfa dosage and/or with phlebotomy, as clinically indicated. Cases of severe hypertension have been observed following overdose with ESAs.

Storage

Store at 2°C to 8°C in a refrigerator. Do not freeze. Do not shake. Keep out of the reach of children.

Commercial pack

Embardia™ 25 mcg Injection: Each box contains 1 pre-filled syringe containing 25 mcg Darbepoetin alfa.

Embardia™ 40 mcg Injection: Each box contains 1 pre-filled syringe containing 40 mcg Darbepoetin alfa.

Embardia™ 60 mcg Injection: Each box contains 1 pre-filled syringe containing 60 mcg Darbepoetin alfa.