



DERISE (Darbepoetin Alfa)

Darbepoetin alfa (INN and generic name; DPO) erythropoiesis stimulating protein and made of 165-amino acid recombinant glycosylated protein produced in Chinese Hamster Ovary (CHO) cell line by recombinant DNA technology.

Dosage Form

It is formulated as a sterile colorless, preservative-free solution for IV and SC administration.

Clinical Pharmacology – Mechanism of Action

DPO differs from rHuEPO in that it contains 5 N-linked oligosaccharide chains and has a molecular weight of 37 kDa and a carbohydrate composition of 51%. These additional chains are accommodated by substitutions at 5 positions along the 165-amino acid backbone, which do not alter the tertiary structure or its biologic activity. The additional carbohydrates result in a longer half-life, increased biologic activity, and decreased receptor affinity.

Human erythropoietin is an endogenous glycoprotein hormone that is the primary regulator of erythropoiesis through specific interaction with the erythropoietin receptor on the erythroid progenitor cells in the bone marrow. The production of erythropoietin primarily occurs in and is regulated by the kidney in response to changes in tissue oxygenation. The production of endogenous erythropoietin is impaired in patients with chronic renal failure, and the primary cause of their anemia is due to erythropoietin deficiency. In patients with cancer receiving chemotherapy, the etiology of anemia is multifactorial. In these patients, erythropoietin deficiency and a reduced response of erythroid progenitor cells to endogenous erythropoietin both contribute significantly to their anemia.

Indication

Several clinical studies have demonstrated that DPO is efficacious in treating anemia in patients with CKD not receiving dialysis when administered at an every-other-week (Q2W) dosing interval. This dosing regimen has proved efficacious both in study patients converting from previous once-weekly (QW) erythropoietic therapy with rHuEPO and in those naive to erythropoietic therapy. Extending the DPO dosing interval may have advantages for both patients and their healthcare providers.

Dosage and Administration

Darbepoetin alfa drug product has the following dose strengths: 10mcg/0.4mL, 15mcg/0.375mL, 20mcg/0.5mL, 25mcg/0.42mL, 40mcg/0.4mL, 60mcg/0.3mL, 100mcg/0.5mL, 150mcg/0.3mL, 200mcg/0.4mL, 300mcg/0.6mL, and 500mcg/1 mL.

The administration is intravenous (IV) and subcutaneous (SC).

Storage and Handling

Derise must be refrigerated at 2°C to 8°C. Protect from light.

Packaging Information

Prefilled syringe with a needle guard.

Manufactured By

M/s. Hetero Biopharma Limited,
Survey No. 458 (Part), TSIC Formulation - SEZ,
Polepally Village, Jadcherla Mandal, Mahaboobnagar District – 509 301,