DARBATITOR

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated prescribing information for **DARBATITOR** (**Darbepoetin alfa Injection**) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Darbepoetin alfa stimulates erythropoiesis by the same mechanism as the endogenous hormone. Darbepoetin alfa has five N-linked carbohydrate chains whereas the endogenous hormone and recombinant human erythropoietins (r-HuEPO) have three. The additional sugar residues are molecularly indistinct from those on the endogenous hormone.

INDICATIONS: It is indicated for the treatment of anemia with chronic renal failure including patients on dialysis and patients not on dialysis.

DOSAGE AND ADMINISTRATION: Darbepoeitin alpha treatment should be initiated by physicians experienced in the above mentioned indications. Darbepoietin alpha should be administered either subcutaneously or intravenously in order to increase haemoglobin to not greater than 12 g/dl (7.5 mmol/l). For chronic renal failure, the initial dose by subcutaneous or intravenous administration is 0.45 µg/kg body weight, as a single injection once weekly.

CONTRAINDICATIONS: Hypersensitivity to the active substance and poorly controlled hypertension.

PRECAUTIONS Cases of severe hypertension, including hypertensive crisis, hypertensive encephalopathy, and seizures, have been observed in CRF patients treated with Darbepoietin alpha. In order to ensure effective erythropoiesis, iron status should be evaluated for all patients prior to and during treatment and supplementary iron therapy may be necessary. Darbepoietin alpha should also be used with caution in those patients with sickle cell anaemia.

DRUG INTERACTIONS: There is potential for an interaction with substances that are highly bound to red blood cells e.g. cyclosporin, Tacrolimus. If Darbepoitin alpha is given concomitantly with any of these treatments, blood levels of these substances should be monitored and the dosage adjusted as the haemoglobin rises.

ADVERSE REACTIONS: Pure red cell aplasia, hypersensitivity, stroke, convulsions, hypertension**,** thromboembolic events, rash/erythema and injection site pain.

MARKETED BY:

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(Additional information is available on request)