PROCRIT (EPOETIN ALFA) for Injection

DESCRIPTION

PROCRIT is a copy of human erythropoietin, a hormone produced primarily by healthy kidneys. PROCRIT replaces the erythropoietin that the failed kidneys can no longer produce, and signals the body to make more red blood cells. PROCRIT is a protein that promotes the growth of red blood cells in the bone marrow, and is indicated for the treatment of anemia associated with chronic renal failure (CRF) in adult patients on dialysis, and for the treatment of anemia associated with dialysis in adult patients with CRF not requiring dialysis. PROCRIT is indicated for patients at high risk for perioperative transfusions with significant, anticipated blood loss. PROCRIT is indicated for adult and pediatric patients with anemia associated with CRF not requiring dialysis, ages 3 months to 20 years, to maintain the red blood cell level (as manifested by the hematocrit or hemoglobin determinations) and to decrease the need for transfusions in these patients. PROCRIT is indicated for adult and pediatric patients with anemia associated with CRF requiring dialysis, ages 3 months to 20 years, to maintain the red blood cell level and to report any changes outside of the guidelines that your doctor has given you. When the number of red blood cells falls below normal levels, you may be more prone to fatigue and shortness of breath. Your doctor will treat your anemia with PROCRIT when your red blood cell levels fall below normal.

PROCRIT is administered by subcutaneous injection or intravenous infusion. The dose and frequency of administration for PROCRIT are determined by your doctor and depend upon the degree of PROCRIT administered and individual patient response.

DOSAGE

The PROCRIT solution in the vial should always be clear and colorless. Do not use if the solution is cloudy or contains visible particles. PROCRIT should be reconstituted with Deionized Water for Injection. The reconstituted solution should be clear and colorless. Do not use if the solution is cloudy or contains visible particles.

Infusion System with Low-Transmission Restrictor

A low transmission restrictor system is also available. The restrictor should be placed in the tubing of the IV infusion set which will be used to administer PROCRIT.

Infusion System without Low-Transmission Restrictor

In patients undergoing coronary artery bypass graft surgery, there were seven deaths in the Epoetin alfa-treated groups (2.9%) compared to five deaths in the placebo group (2.1%). The difference in the proportion of all patients treated with PROCRIT who died was statistically significant (P = 0.03). The proportion of patients treated with Epoetin alfa who died was 4.6% and the proportion of placebo-treated patients who died was 3.3%.

PROCRIT was also studied in an open-label, parallel-group trial enrolling 145 subjects with a pretreatment hematocrit of 15% to 25% and a serum creatinine level of 2.5 to 4.0 mg/dL (133 to 286 μmol/L) and a serum creatinine level of 1.5 to 2.5 mg/dL (86 to 143 μmol/L). The patients were randomized to receive PROCRIT 600 U/kg weekly or PROCRIT 300 U/kg daily for 12 weeks. The mean increase in absolute reticulocyte count at the end of the study was greater than observed in the 300 U/kg daily group. The mean increase in absolute reticulocyte count was also greater than the increase observed in the placebo group. The mean increase in absolute reticulocyte count was 19.0 ± 5.9 hours (mean ± SD) in the placebo group.

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Increases in blood pressure have been reported in clinical trials, often during the first 90 days of therapy. In patients treated with PROCRIT®, evidence of hypertension, defined as systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90 mm Hg, was more frequent than in placebo-treated patients. In a clinical trial of patients with CRF not on dialysis, 10% of PROCRIT-treated patients and 2% of placebo-treated patients had hypertension. The median duration of PROCRIT therapy in this trial was 10 weeks following dose increases. At least 10% of patients treated with PROCRIT® had diastolic blood pressure ≥90 mm Hg or systolic blood pressure ≥140 mm Hg. Of the patients who required treatment discontinuation due to hypertension, 10% of patients treated with PROCRIT® had diastolic blood pressure ≥90 mm Hg or systolic blood pressure ≥140 mm Hg. In adult patients with CRF not on dialysis, the maintenance dose must be increased by 50-100 Units/kg (T.I.W.) if the transferrin saturation is less than 20%. In adult patients with CRF not on dialysis, the maintenance dose must be increased by 50-100 Units/kg (T.I.W.) if the transferrin saturation is less than 20%. In adult patients with CRF not on dialysis, the maintenance dose must be increased by 50-100 Units/kg (T.I.W.) if the transferrin saturation is less than 20%. In adult patients with CRF not on dialysis, the maintenance dose must be increased by 50-100 Units/kg (T.I.W.) if the transferrin saturation is less than 20%. In adult patients with CRF not on dialysis, the maintenance dose must be increased by 50-100 Units/kg (T.I.W.) if the transferrin saturation is less than 20%. In adult patients with CRF not on dialysis, the maintenance dose must be increased by 50-100 Units/kg (T.I.W.) if the transferrin saturation is less than 20%. In adult patients with CRF not on dialysis, the maintenance dose must be increased by 50-100 Units/kg (T.I.W.) if the transferrin saturation is less than 20%. In adult patients with CRF not on dialysis, the maintenance dose must be increased by 50-100 Units/kg (T.I.W.) if the transferrin saturation is less than 20%. In adult patients with CRF not on dialysis, the maintenance dose must be increased by 50-100 Units/kg (T.I.W.) if the transferrin saturation is less than 20%. In adult patients with CRF not on dialysis, the maintenance dose must be increased by 50-100 Units/kg (T.I.W.) if the transferrin saturation is less than 20%.