

Epogen®/Procrit® (epoetin alfa) – New warnings

- On September 29, 2017, the FDA approved updates to the *Warnings and Precautions* section of the [Epogen/Procrit \(epoetin alfa\)](#) drug label regarding severe cutaneous reactions and risk of serious adverse reactions due to benzyl alcohol preservative.
- Epoetin alfa is indicated for the following:
 - Treatment of anemia due to chronic kidney disease, including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion.
 - Treatment of anemia due to [zidovudine](#) administered at ≤ 4200 mg/week in patients with human immunodeficiency virus infection with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL.
 - Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
 - To reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin > 10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. Epoetin alfa is not indicated for patients who are willing to donate autologous blood preoperatively.
- Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being. Epoetin alfa is not indicated for use:
 - In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
 - In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
 - In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion.
 - In patients scheduled for surgery who are willing to donate autologous blood.
 - In patients undergoing cardiac or vascular surgery.
 - As a substitute for RBC transfusions in patients who require immediate correction of anemia.
- Information regarding severe cutaneous reactions was added to the *Warnings and Precautions* section of the Epogen/Procrit drug label.
 - Blistering and skin exfoliation reactions including erythema multiforme and Stevens-Johnson Syndrome (SJS)/toxic epidermal necrolysis (TEN), have been reported in patients treated with erythropoiesis-stimulating agents (ESAs) (including epoetin alfa) in the postmarketing setting.
 - Epoetin alfa should be discontinued immediately if severe cutaneous reactions, such as SJS/TEN are suspected.
- Information regarding risk of serious adverse reactions due to benzyl alcohol preservative was also added to the *Warnings and Precautions* section of the Epogen/Procrit drug label.
 - Epoetin alfa from multiple-dose vials contains benzyl alcohol and is contraindicated for use in neonates, infants, pregnant women, and lactating women.
 - Epoetin alfa should not be mixed with bacteriostatic saline (which also contains benzyl alcohol) when administering epoetin alfa to these patient populations.

- Serious and fatal reactions including “gaspings syndrome” can occur in neonates and infants treated with benzyl alcohol-preserved drugs, including epoetin alfa multiple-dose vials.
 - “Gaspings syndrome” is characterized by central nervous system depression, metabolic acidosis, and gasping respirations. There is a potential for similar risks to fetuses and infants exposed to benzyl alcohol in utero or in breast-fed milk, respectively.
 - The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known.
- Information regarding laboratory monitoring was removed from the *Warnings and Precautions* section.
 - Epoetin alfa carries a boxed warning stating that ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence.



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