

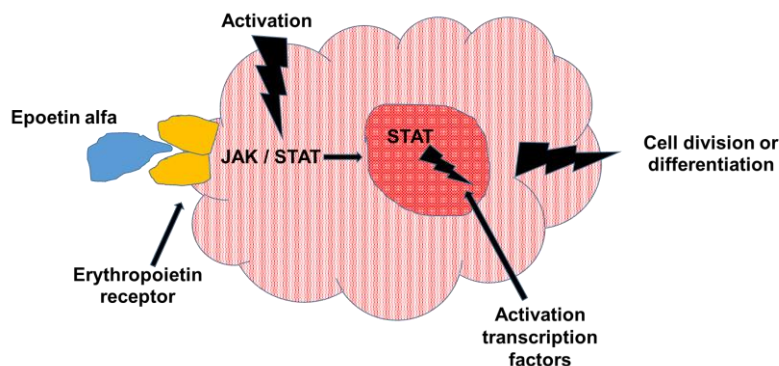
Epoetin Alfa – Fact Sheet

Molecule

Epoetin alfa (Epogen® / Eprex® / Procrit®) contains 165 amino acids with the identical sequence of naturally occurring erythropoietin. It has a molecular weight of approximately 30.4 kDa. Epoetin alfa and epoetin beta have differences in the glycosylation pattern.

Mode of Action

Epoetin alfa stimulates erythropoiesis by the same mechanism as endogenous erythropoietin. Erythropoietin interacts with progenitor stem cells to increase red cell production. Binding of erythropoietin to the erythropoietin receptor leads to receptor dimerization, which facilitates activation of janus kinase - signal transducers and activators of transcription (JAK-STAT) signaling pathways within cell cytosol. Activated STAT proteins are translocated to the nucleus where they function as transcription factors, which regulate the activation of specific genes involved in cell division or differentiation process.



Indication

Epogen® is indicated for the treatment of anemia due to chronic kidney disease, anemia due to zidovudine in patients with HIV infection, treatment of patients with non-myeloid malignancies, and for reduction of the need for allogeneic red blood cell transfusions during elective, noncardiac, nonvascular surgery.

Patent Situation

The patents on Epogen® / Eprex® have been expired in US and Europe already in 2013.

Market and Competitive Field

The originator product of Amgen (Epogen®) and Johnson & Johnson (Eprex® / Procrit®) was approved for its first indication by FDA and EMA in 1989. Epogen® and Eprex® / Procrit® had worldwide sales of 2.7 billion € in 2015 (1.7 billion € for Amgen and 1.0 billion € for Johnson & Johnson). Due to competition from biosimilars, sales are steadily declining: 504 / 465 million € in 2020, whereas sales of biosimilar Retacrit® (Pfizer) were already 325 million €.

	Epoetin Alfa
	Epogen®, Eprex®
	Abseamed®, Retacrit®, Binocrit® *
Clone selection / comparability	
Affinity to recombinant target – kinetics (Biacore)	
Cell-based bioassay	
(Pre)clinical application	
Pharmacokinetics (ECL or ELISA)	
Immunogenicity (Biacore / ELISA / bioassay)	
Batch release EU	

*Examples for tradenames of biosimilar products

