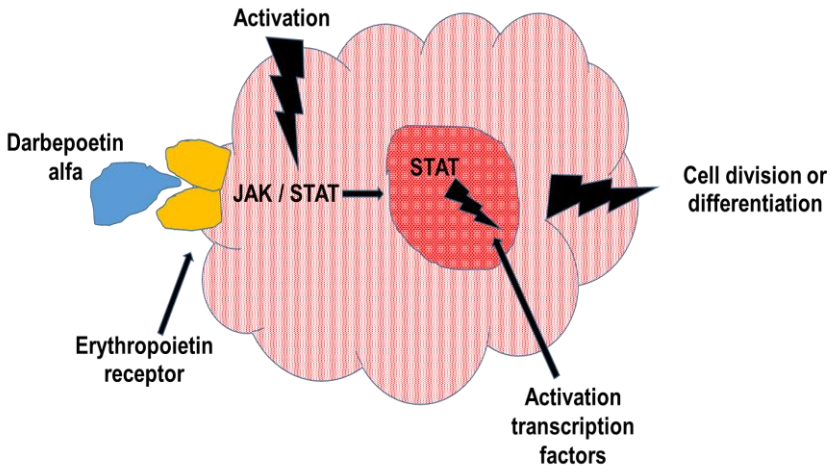
Darbepoetin Alfa – Fact Sheet

Molecule

Darbepoetin alfa (Aranesp®) contains in comparison to natural erythropoietin five amino acid changes (at N30, T32, V87, N88, T90) resulting into creation of two new sites for N-linked carbohydrate addition. It has a three-fold longer serum half-life as compared to epoetin alpha and epoetin beta. It is a 165-amino acid protein with a molecular weight of 37 kDa.

Mode of Action

Darbepoetin 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 cellular 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

Aranesp® is indicated for the treatment of anemia due to chronic kidney disease, including patients on dialysis and patients not on dialysis. Aranesp® is also indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelo-suppressive chemotherapy.

Patent Situation

Patents on Aranesp® will expire in US in May 2024 and already expired in Europe in July 2016.

Market and Competitive Field

The originator product, Amgen's Aranesp®, was approved by FDA and EMA in 2001. Amgen co-developed the product with Kyowa Hakko Kirin (Japan), which sells the drug in Japan and other Asian countries as Nesp®. In 2020, Aranesp® had sales of 1.32 billion €, which slightly increased to 1.37 billion € in 2021. Biosimilars are marketed in Japan and in India.

VelaLabs GmbH
Brunner Straße 69 / Obj. 3, A-1230 Vienna / Austria
Phone: +43 1 890 5979 11, Fax: +43 1 890 5979 10
E-Mail: office@vela-labs.at

	Darbepoetin Alfa
	Aranesp®, Nesp®
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	

Vela Portfolio

If you are interested in the full version including patent and originator data please contact us: velabd@vela-labs.at