



AMGEN ESAs

A Commitment to Support

Indications

Aranesp® (darbepoetin alfa) is indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis.

EPOGEN® (epoetin alfa) is indicated for the treatment of anemia due to chronic kidney disease (CKD) in patients on dialysis to decrease the need for red blood cell (RBC) transfusion.

Limitations of Use:

- Aranesp® and EPOGEN® have not been shown to improve quality of life, fatigue, or patient well-being.
- Aranesp® and EPOGEN® are not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

*Please see Important Safety Information for Aranesp® and EPOGEN® including **Boxed WARNINGS** about **INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE**, on pages 6-7.*



Vials shown are not actual size



For over 30 years, Amgen has demonstrated a commitment to the nephrology community. Amgen continues to provide a wide range of resources to support patient care.

Amgen is committed to comprehensive support



Amgen sales support team

Your sales team and key account managers are your source of support for any questions about ordering or details about Aranesp® and/or EPOGEN®.

Amgen Engagement Center

[1-877-255-1114](tel:1-877-255-1114)



Coverage and reimbursement support

An Amgen reimbursement specialist can assist you with insurance verification, co-pays, and reimbursement resources.

Amgen Assist®

[1-800-272-9376](tel:1-800-272-9376)



Resources for your practice

Reinforce your understanding of anemia in CKD and build your treatment knowledge with virtual education programs from your Amgen inside sales team.

[Questions about your order or account >](#)
call 855-4-ANEMIA

AnemiaHub.com

A comprehensive one-stop support and on-demand resources for anemia management education, especially for nephrologists to share with patients or to become better informed.

Amgen Anemia Management Institute (AMI)® Virtual In-Service Presentations

Educational materials to stimulate critical thinking in anemia management.

- All presentations are appropriate for Anemia Managers, nurses, dietitians, and dialysis technicians
- All modules can be delivered in a half hour or less

WARNING: ESAs INCREASE THE RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE

Chronic Kidney Disease:

- In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL.
- No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks.
- Use the lowest Aranesp® or EPOGEN® dose sufficient to reduce the need for red blood cell (RBC) transfusions.

Cancer:

- ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.
- To decrease these risks, as well as the risk of serious cardiovascular and thromboembolic reactions, use the lowest dose needed to avoid RBC transfusions.
- Use ESAs only for anemia from myelosuppressive chemotherapy.
- ESAs are not indicated for patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
- Discontinue following the completion of a chemotherapy course.

Perisurgery (EPOGEN®):

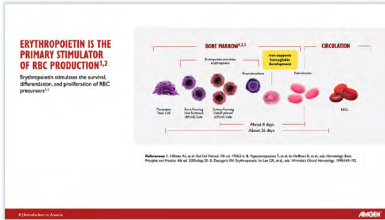
- Due to increased risk of Deep Venous Thrombosis (DVT), DVT prophylaxis is recommended.

Please see Important Safety Information for Aranesp® and EPOGEN® including Boxed WARNINGS about INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE, on pages 6-7.

Anemia Management Institute (AMI)[®] In-Service Modules Overview

General Anemia Education

Introduction to Anemia

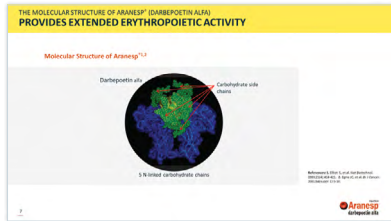


- Explains red blood cell production and introduces concept of erythropoiesis
- Explains how anemia of chronic kidney disease develops and importance of managing low hemoglobin
- Cites lab values to monitor and the impact that unpredictable clinical events have on these lab values

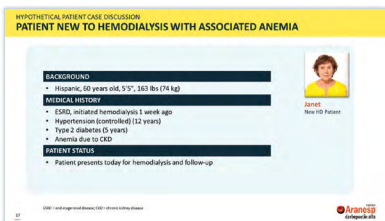
Aranesp[®] (darbepoetin alfa) Educational Modules

About Aranesp[®]

- Overview of Aranesp[®] clinical experience and longevity in the marketplace
- Reviews mechanism of action, dosing guidelines, and basic principles of anemia management
- Provide SKUs and other ordering information needed for Aranesp[®]



Aranesp[®] Use in Appropriate Patients New to Hemodialysis and Peritoneal Dialysis



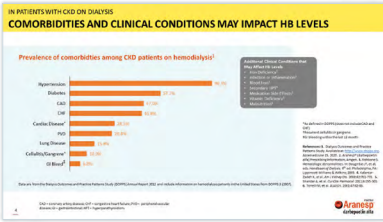
- Includes two hypothetical case studies, one for patients new to hemodialysis and one for patients new to peritoneal dialysis
- More detail into principles of anemia management (Trend/Predict/Intervene approach)
- Reviews PI dosing and making dose adjustments with Aranesp[®]

Important Safety Information for Aranesp[®] (darbepoetin alfa) and EPOGEN[®] (epoetin alfa), including Boxed WARNINGS

- Aranesp[®] and EPOGEN[®] are contraindicated in patients with:
 - Uncontrolled hypertension
 - Pure red cell aplasia (PRCA) that begins after treatment with Aranesp[®], EPOGEN[®], or other erythropoietin protein drugs
 - Serious allergic reactions to Aranesp[®] or EPOGEN[®]

Please see Important Safety Information for Aranesp[®] and EPOGEN[®] including **Boxed WARNINGS** about **INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE**, on pages 6-7.

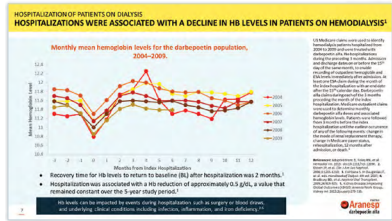
Managing Hemoglobin Levels in CKD Patients: Treatment of Anemia Due to CKD Including Patients With Multiple Comorbidities



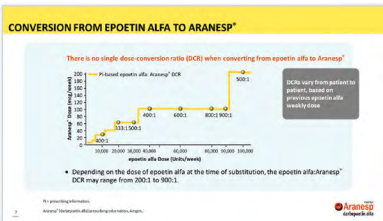
- One hypothetical case study of a patient with comorbid conditions
- Explains how comorbid conditions and unpredictable clinical events impact anemia, hemoglobin levels, and overall facility outcomes
- Explains how Aranesp® lends toward timely intervention during these unpredictable clinical events

Aranesp® Use in Managing Hemoglobin Level Changes: Treatment of Anemia Due to CKD Including Patients Post Hospitalization and Peritoneal Dialysis

- One hypothetical case study of a post hospitalized patient
- Explains causes and lengths of stay for patients on dialysis and impact to hemoglobin levels
- Explains anemia management of a post hospitalized patient upon return to dialysis



Managing Anemia in Patients Converting From Epoetin Alfa to Aranesp®



- One hypothetical case study of converting a patient from epoetin alfa to Aranesp®
- Explains conversion from epoetin alfa to Aranesp®, citing examples
- Reaffirms the dosing, safety, and efficacy of Aranesp®

CKD = chronic kidney disease; SKU = stock keeping unit.

Important Safety Information for Aranesp® (darbepoetin alfa) and EPOGEN® (epoetin alfa), including Boxed WARNINGS

- EPOGEN® from multidose vials contains benzyl alcohol and is contraindicated in neonates, infants, pregnant women, and lactating women.
- Use caution in patients with coexistent cardiovascular disease and stroke

Please see Important Safety Information for Aranesp® and EPOGEN® including **Boxed WARNINGS** about **INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE**, on pages 6-7.

Aranesp® (darbepoetin alfa) and EPOGEN® (epoetin alfa) Indications and Important Safety Information, including Boxed WARNINGS

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Important Safety Information, including Boxed WARNINGS

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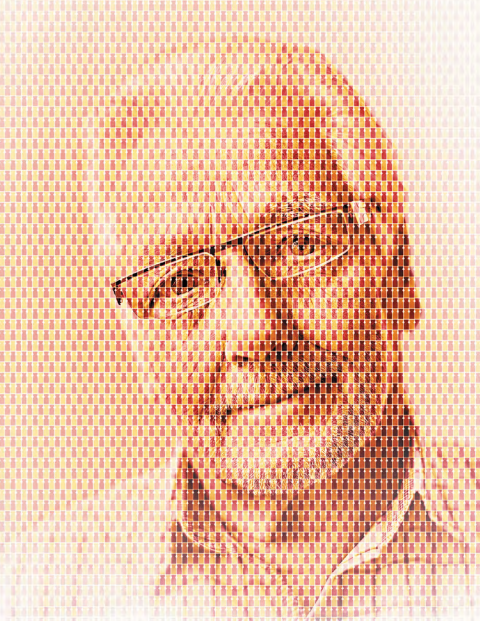
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- Use caution in patients with coexistent cardiovascular disease and stroke.
- Patients with CKD and an insufficient hemoglobin response to ESA therapy may be at even greater risk for cardiovascular reactions and mortality than other patients. A rate of hemoglobin rise of > 1 g/dL over 2 weeks may contribute to these risks.
- In controlled clinical trials, ESAs increased the risk of death in patients undergoing coronary artery bypass graft surgery (CABG) and the risk of deep venous thrombosis (DVT) in patients undergoing orthopedic procedures.
- Control hypertension prior to initiating and during treatment with Aranesp® or EPOGEN®.
- Aranesp® and EPOGEN® increase the risk of seizures in patients with CKD. Monitor patients closely for new-onset seizures, premonitory symptoms, or change in seizure frequency.
- For lack or loss of hemoglobin response to Aranesp® or EPOGEN®, initiate a search for causative factors. If typical causes of lack or loss of hemoglobin response are excluded, evaluate for PRCA.
- Cases of PRCA and of severe anemia, with or without other cytopenias that arise following the development of neutralizing antibodies to erythropoietin have been reported in patients treated with Aranesp® or EPOGEN®.
 - This has been reported predominantly in patients with CKD receiving ESAs by subcutaneous administration.
 - PRCA has also been reported in patients receiving ESAs for anemia related to hepatitis C treatment (an indication for which Aranesp® and EPOGEN® are not approved).
 - If severe anemia and low reticulocyte count develop during treatment with Aranesp® or EPOGEN®, withhold Aranesp® or EPOGEN® and evaluate patients for neutralizing antibodies to erythropoietin.
 - Permanently discontinue Aranesp® or EPOGEN® in patients who develop PRCA following treatment with Aranesp®, EPOGEN®, or other erythropoietin protein drugs. Do not switch patients to other ESAs.
- Serious allergic reactions, including anaphylactic reactions, angioedema, bronchospasm, skin rash, and urticaria may occur with Aranesp® or EPOGEN®. Immediately and permanently discontinue Aranesp® or EPOGEN® if a serious allergic reaction occurs.
- Blistering and skin exfoliation reactions including Erythema multiforme and Stevens-Johnson Syndrome (SJS)/Toxic Epidermal Necrolysis (TEN), have been reported in patients treated with ESAs (including Aranesp® and EPOGEN®) in the postmarketing setting. Discontinue Aranesp® or EPOGEN® therapy immediately if a severe cutaneous reaction, such as SJS/TEN, is suspected.
- Serious and fatal reactions including “gaspings syndrome” can occur in neonates and infants treated with benzyl alcohol-preserved drugs, including EPOGEN® multiple-dose vials. There is a potential for similar risks to fetuses and infants exposed to benzyl alcohol in utero or in breast-fed milk, respectively.
- Adverse reactions (≥ 10%) in Aranesp® clinical studies in patients with CKD were hypertension, dyspnea, peripheral edema, cough, and procedural hypotension.
- Adverse reactions (≥ 5%) in EPOGEN® clinical studies in patients with CKD were hypertension, arthralgia, muscle spasm, pyrexia, dizziness, medical device malfunction, vascular occlusion, and upper respiratory tract infection.

*Please click for the full [Prescribing Information](#), including **BOXED WARNINGS**, and the [Medication Guide](#).*

Amgen support and services demonstrate a commitment to the **Nephrology Community**



- Comprehensive support with a consistent supply of Aranesp® and EPOGEN® for patients since 2001^{1,*}
- Committed to training, education, and reimbursement support

*Based on product shipped to Amgen Authorized Distributors of Record in 99.9% of possible weeks from 10/01/01 to 4/03/17.

Visit anemiahub.com for more anemia management educational materials

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Reference: 1. Data on file, Amgen; [Historic Aranesp® and EPOGEN® Shipment Summary; March 8, 2021].



AMGEN

Nephrology

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Vials shown are not actual size