Vafseo® (vadadustat) Tablets

How might an oral option benefit adults with anemia due to CKD on peritoneal dialysis?[1]

Needle-free dosing

Taken at home or on the go*

Designed to fit into their daily schedule

Vafseo can help treat anemia due to CKD in adults receiving dialysis for at least 3 months.[2]

SEE WHO MAY BENEFIT FROM TREATMENT WITH ORAL VAFSEO

CKD=chronic kidney disease.
*Please see important monitoring assessments within the accompanying Full Prescribing Information.

INDICATION

VAFSEO is indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months.

Limitations of Use

- VAFSEO has not been shown to improve quality of life, fatigue, or patient well-being.
- VAFSEO is not indicated for use:
  - As a substitute for red blood cell transfusions in patients who require immediate correction of anemia.
  - In patients with anemia due to CKD not on dialysis.

IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat) tablets

WARNING: INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, and THROMBOSIS OF VASCULAR ACCESS.

VAFSEO increases the risk of thrombotic vascular events, including major adverse cardiovascular events (MACE).

Targeting a hemoglobin level greater than 11 g/dL is expected to further increase the risk of death and arterial and venous thrombotic events, as occurs with erythropoietin stimulating agents (ESAs), which also increase erythropoietin levels.

No trial has identified a hemoglobin target level, dose of VAFSEO, or dosing strategy that does not increase these risks.

Use the lowest dose of VAFSEO sufficient to reduce the need for red blood cell transfusions.

Please see additional Important Safety Information throughout and click here for the Full Prescribing Information, including BOXED WARNING and Medication Guide.

meet Valerie

A 54-year-old operations manager, diagnosed with anemia due to CKD

Hypothetical patient profile. Not an actual patient.

medical history	lab results	current treatment
History of diabetes mellitus	**Hb Level:** 9.6 g/dL	Undergoing at-home peritoneal dialysis treatment (6 months)
No history of uncontrolled hypertension, liver disease, or active malignancy	**Iron Status:** TSAT=29% Serum ferritin=448 ng/mL	Traveling to a clinic for her IV iron
Experienced a myocardial infarction 5 months ago		Visiting a clinic every 2 weeks for her ESA injections (4 months)

CKD=chronic kidney disease; ESA=erythropoiesis-stimulating agent; Hb=hemoglobin; HIF-PHI=hypoxia-inducible factor prolyl hydroxylase inhibitor; IV=intravenous; TSAT=transferrin saturation.

IMPORTANT SAFETY INFORMATION (cont.)

CONTRAINDICATIONS

- Known hypersensitivity to VAFSEO or any of its components
- Uncontrolled hypertension

WARNINGS AND PRECAUTIONS

- **Increased Risk of Death, Myocardial Infarction (MI), Stroke, Venous Thromboembolism, and Thrombosis of Vascular Access**
  A rise in hemoglobin (Hb) levels greater than 1 g/dL over 2 weeks can increase these risks. Avoid in patients with a history of MI, cerebrovascular event, or acute coronary syndrome within the 3 months prior to starting VAFSEO. Targeting a Hb level of greater than 11 g/dL is expected to further increase the risk of death and arterial and venous thrombotic events. Use the lowest effective dose to reduce the need for red blood cell (RBC) transfusions. Adhere to dosing and Hb monitoring recommendations to avoid excessive erythropoiesis.
- **Hepatotoxicity**
  Hepatocellular injury attributed to VAFSEO was reported in less than 1% of patients, including one severe case with jaundice. Elevated serum ALT, AST, and bilirubin levels were observed in 1.8%, 1.8%, and 0.3% of CKD patients treated with VAFSEO, respectively. Measure ALT, AST, and bilirubin before treatment and monthly for the first 6 months, then as clinically indicated. Discontinue VAFSEO if ALT or AST is persistently elevated or accompanied by elevated bilirubin. Not recommended in patients with cirrhosis or active, acute liver disease.

Please see additional Important Safety Information throughout and click here for the Full Prescribing Information, including BOXED WARNING and Medication Guide.

Vafseo®
(vadadustat) Tablets

"With the constant travel and time off work for treatment, **managing my anemia has been challenging.**"

Hypothetical patient profile.
Not an actual patient.

Discover Vafseo—a HIF-PHI studied in a wide range of adult patients on dialysis, including peritoneal dialysis[2,3]

IMPORTANT SAFETY INFORMATION (cont.)
WARNINGS AND PRECAUTIONS (cont.)

- **Hypertension**
  Worsening of hypertension was reported in 14% of VAFSEO and 17% of darbepoetin alfa patients. Serious worsening of hypertension was reported in 2.7% of VAFSEO and 3% of darbepoetin alfa patients. Cases of hypertensive crisis, including hypertensive encephalopathy and seizures, have also been reported in patients receiving VAFSEO. Monitor blood pressure. Adjust anti-hypertensive therapy as needed.
- **Seizures**
  Seizures occurred in 1.6% of VAFSEO and 1.6% of darbepoetin alfa patients. Monitor for new-onset seizures, premonitory symptoms, or change in seizure frequency.
- **Gastrointestinal (GI) Erosion**
  Gastric or esophageal erosions occurred in 6.4% of VAFSEO and 5.3% of darbepoetin alfa patients. Serious GI erosions, including GI bleeding and the need for RBC transfusions, were reported in 3.4% of VAFSEO and 3.3% of darbepoetin alfa patients. Consider this risk in patients at increased risk of GI erosion. Advise patients about signs of erosions and GI bleeding and urge them to seek prompt medical care if present.

Please see additional Important Safety Information throughout and click here for the Full Prescribing Information, including BOXED WARNING and Medication Guide.

"The approval of Vafseo offers a different way to

correct and maintain Hb to target levels for our appropriate, at-home dialysis patients with anemia."

Vafseo® (vadadustat) Tablets

Ashte Collins, MD, Chief of Nephrology and Hypertension, Associate Professor of Medicine, GW School of Medicine, Washington, DC

Dr Collins is a paid consultant for Akebia Therapeutics.

HOW MANY OF YOUR APPROPRIATE PATIENTS ON PD COULD BENEFIT FROM TREATMENT WITH ORAL VAFSEO?[1]

PD=peritoneal dialysis.

IMPORTANT SAFETY INFORMATION (cont.)
WARNINGS AND PRECAUTIONS (cont.)

- **Serious Adverse Reactions in Patients with Anemia Due to CKD and Not on Dialysis**

  The safety of VAFSEO has not been established for the treatment of anemia due to CKD in adults not on dialysis and its use is not recommended in this setting. In large clinical trials in adults with anemia of CKD who were not on dialysis, an increased risk of mortality, stroke, MI, serious acute kidney injury, serious hepatic injury, and serious GI erosions was observed in patients treated with VAFSEO compared to darbepoetin alfa.

- **Malignancy**

  VAFSEO has not been studied and is not recommended in patients with active malignancies. Malignancies were observed in 2.2% of VAFSEO and 3.0% of darbepoetin alfa patients. No evidence of increased carcinogenicity was observed in animal studies.

ADVERSE REACTIONS

- The most common adverse reactions (occurring at ≥ 10%) were hypertension and diarrhea.

DRUG INTERACTIONS

- **Iron supplements and iron-containing phosphate binders:** Administer VAFSEO at least 1 hour before products containing iron.
- **Non-iron-containing phosphate binders:** Administer VAFSEO at least 1 hour before or 2 hours after non-iron-containing phosphate binders.
- **BCRP substrates:** Monitor for signs of substrate adverse reactions and consider dose reduction.
- **Statins:** Monitor for statin-related adverse reactions. Limit the daily dose of simvastatin to 20 mg and rosuvastatin to 5 mg.

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm.
- Lactation: Breastfeeding not recommended until two days after the final dose.
- Hepatic Impairment: Not recommended in patients with cirrhosis or active, acute liver disease.

Please note that this information is not comprehensive. Please see additional Important Safety Information throughout and click here for the Full Prescribing Information, including BOXED WARNING and Medication Guide.

References: 1. Sarnak MJ, Agarwal R, Boudville N, et al. Vadadustat for treatment of anemia in patients with dialysis-dependent chronic kidney disease receiving peritoneal dialysis. *Nephrol Dial Transplant*. 2023;38(10):2358-2367. doi:10.1093/ndt/gfad074 **2.** Vafseo® [Package Insert]. Cambridge, MA: Akebia Therapeutics, Inc. **3.** Eckardt KU, Agarwal R, Aswad A, et al. Safety and efficacy of vadadustat for anemia in patients undergoing dialysis. *N Engl J Med*. 2021;384(17):1601-1612. doi:10.1056/NEJMoa2025956

Akebia® THERAPEUTICS

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