

For adults with anemia due to chronic kidney disease (CKD) on dialysis for at least 3 months¹

Vafseo dosing checklist for dialysis care teams

Discover checklists for the pretreatment, treatment initiation, and dose titration of Vafseo.

Not actual size.



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.

Evaluations and tests prior to starting Vafseo¹

Pretreatment

- ✓ Confirm patient has no contraindications for use
- ✓ Correct and exclude other causes of anemia and check iron stores
- ✓ Measure Hb
- ✓ Perform liver tests (serum ALT, AST, and bilirubin)
- ✓ Check for potential drug-related interactions (eg, iron/phosphate binders, simvastatin, rosuvastatin)
- ✓ Set expectations based on the patient's clinical conditions, including previous ESA use

Treatment initiation

Patient may receive Vafseo regardless of the type of dialysis they receive.

- ✓ Start Vafseo at 300 mg by mouth once daily
- ✓ Administer Vafseo without regard to the timing of dialysis
- ✓ Inform patient that Vafseo can be taken with or without food
- ✓ Remind patient that if a dose of Vafseo is missed, it should be taken as soon as possible, unless it is the same day as the next dose

On-treatment considerations for Vafseo¹

Dose titration

- ✓ Monitor Hb and liver function
- ✓ Adjust dose in increments of 150 mg up to 600 mg to achieve or maintain Hb of 10-11 g/dL*
- ✓ Increase the dose no more frequently than once every 4 weeks. Decreases in dose can occur more frequently
- ✓ Use the lowest dose sufficient to reduce the need for RBC transfusions

*Do not target Hb level higher than 11 g/dL.

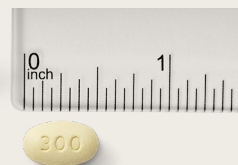


For more information on Vafseo dosing, including rescue, treatment interruption, discontinuation, and drug interactions, please refer to the Full Prescribing Information.

ALT=alanine aminotransferase; AST=aspartate aminotransferase; ESA=erythropoiesis-stimulating agent; Hb=hemoglobin; RBC=red blood cell.

Vafseo[®]
(vadadustat) Tablets

**Vafseo is available in 2 dosing strengths:
150-mg tablets and 300-mg tablets¹**



IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat) tablets (Cont'd)

CONTRAINDICATIONS

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

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

**IMPORTANT SAFETY INFORMATION about
VAFSEO (vadadustat) tablets (Cont'd)**

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.

• **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.

**IMPORTANT SAFETY INFORMATION about
VAFSEO (vadadustat) tablets (Cont'd)**

WARNINGS AND PRECAUTIONS (Cont'd)

• **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.

• **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 $\geq 10\%$) 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.

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

Vafseo[®] (vadadustat) Tablets



For complete dosing and administration information, visit VafseoHCP.com to learn more.

IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat) tablets (Cont'd)

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.

Reference: 1. Vafseo[®] [Package Insert]. Cambridge, MA: Akebia Therapeutics, Inc.

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