

If you are an adult with anemia caused by chronic kidney disease (CKD) and have been on dialysis for at least 3 months

# Vafseo® (vadadustat) is a once-daily pill that helps manage anemia—and it's not an injection\*

Most people with CKD who are on dialysis are at risk of having anemia now or in the future

## HOW VAFSEO WORKS

Vafseo (VAF-fsee-oh) works by helping increase a protein called erythropoietin (EPO), a key part of the body's natural process of making red blood cells (RBCs). Vafseo is used to reduce or avoid the need for RBC transfusions.

\*Number of Vafseo pills per day will be dependent on your dose.



## APPROVED USE

VAFSEO (vadadustat) is a prescription medicine used to treat anemia caused by chronic kidney disease (CKD) in adults who have been on dialysis for at least three months.

VAFSEO has not been proven to improve quality of life, tiredness (fatigue), or well-being.

VAFSEO **should not be used:**

- in place of emergency treatment for anemia (red blood cell transfusions)
- for the treatment of anemia that is caused by CKD in people who are not on dialysis

## IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat)

### MOST IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT VAFSEO

VAFSEO may cause serious side effects, including:

**Increased risk of death, heart attack, stroke, and blood clots.** These risks may happen if you are treated with VAFSEO to increase red blood cells (RBCs) to near the same level found in healthy people. These risks may be increased if you have heart or blood vessel problems, or problems with blood flow to your brain. Blood clots can form in the blood vessels, including your legs, lungs, and in your dialysis access.

**Get medical help right away if you get any of the following signs or symptoms:** chest pain; trouble breathing or shortness of breath; cold sweat; sudden numbness or weakness in your face, arm or leg, especially on one side of your body; sudden confusion, trouble speaking, or trouble understanding others' speech; sudden trouble seeing; sudden trouble walking, dizziness, loss of balance or coordination; loss of consciousness (fainting); severe headache; pain in your legs, with or without swelling; a cool or pale arm or leg; changes to your dialysis access site, including swelling or discoloration near the site; do not feel a vibration ("thrill") over the dialysis access area.

If you decide to take VAFSEO, your healthcare provider should prescribe the lowest dose of VAFSEO that is necessary to reduce your chance of needing red blood cell transfusions.

Please see additional Important Safety Information throughout, and on page 7. Please [click here](#) for the Full Prescribing Information, including BOXED WARNING and Medication Guide or visit [Vafseo.com](http://Vafseo.com).

**Vafseo**  
(vadadustat) Tablets

For adults with anemia caused by CKD who have been on dialysis for at least 3 months

# Why you might need Vafseo® (vadadustat) to help control anemia

## Your kidneys play an important part in helping the whole body function

- Your kidneys help make a protein called erythropoietin (pronounced “eh-ri-thruh-poi-e-tin”) or “EPO”, which is part of the body’s natural way of creating red blood cells (RBCs)
- RBCs contain a protein called hemoglobin (Hb), which carries oxygen throughout your body, for your tissues and organs to function properly
- In chronic kidney disease (CKD), your kidneys may have trouble making EPO, which can also mean your body has less RBCs



**Anemia is important to treat to reduce the need for RBC transfusions. In severe cases, RBC transfusions are used to quickly treat anemia in CKD, but can impact your long-term health outcomes. Talk to your doctor about the possible impact of RBC transfusions.**

## Anemia is common in patients with CKD, and can worsen as kidney function declines

- Anemia is a condition where your body does not make enough RBCs, so the body has less Hb to give the body the oxygen it needs
- People with CKD can often have anemia due to low EPO
- Signs of anemia include feeling extra tired, looking pale, or feeling out of breath. Many of these can have multiple causes. Talk to your doctor if you have any of these signs, so they can properly diagnose you

## IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat) (cont.)

### DO NOT USE VAFSEO IF YOU:

- are allergic to vadadustat or any of the ingredients in VAFSEO. Refer to the Medication Guide for a complete list of ingredients in VAFSEO.
- have high blood pressure that is not controlled (uncontrolled hypertension).

Please see additional Important Safety Information throughout, and on page 7. Please [click here](#) for the Full Prescribing Information, including BOXED WARNING and Medication Guide or visit [Vafseo.com](https://www.vafseo.com).

For adults with anemia caused by CKD who have been on dialysis for at least 3 months

# With Vafseo® (vadadustat), you and your doctor can help control anemia

## Fight anemia caused by CKD with Vafseo

- In 2 clinical studies in adults with anemia due to CKD and on dialysis, Vafseo showed results similar to a treatment called an erythropoietin-stimulating agent (ESA),\* which is also used to treat anemia caused by CKD. ESAs are injected subcutaneously or given intravenously (IV)
- Vafseo helped raise Hb levels and keep them within the recommended range; individual results may vary
- Vafseo may cause serious side effects, including increased risk of death, heart attack, stroke, and blood clots. This is not a full list of the possible side effects of Vafseo. See page 7 for more information

\*The generic name of the ESA used in these studies is darbepoetin alfa.

## How Vafseo works

**1** Vafseo helps your body make more of its own EPO, which helps make more RBCs



**2** More RBCs mean more Hb to carry oxygen throughout your body for tissues and organs to function properly

## Talk with your doctor about what to expect during treatment

- It is important to take your medicine every day as directed by your doctor, keep up with your appointments and blood tests, and to regularly talk with your doctor about how you are feeling
- Your doctor will check your Hb levels when you start treatment and every two weeks until stable, then at least monthly. Your doctor may change your dose depending on how your body responds to the medicine

## IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat) (cont.)

### WARNINGS

**VAFSEO may cause other serious side effects, including:**

**Liver problems.** VAFSEO may cause changes in blood liver tests, which may be a sign of liver injury. Your healthcare provider will do blood liver tests before starting treatment with VAFSEO, monthly for the first 6 months and then as needed. Your healthcare provider may stop treatment with VAFSEO if you have changes in your blood liver tests. Tell your healthcare provider if you experience: tiredness; loss of appetite; pain in your right upper stomach area (abdomen); dark urine; yellowing of your skin or the white part of your eyes.

**Please see additional Important Safety Information throughout, and on page 7.**  
**Please [click here](#) for the Full Prescribing Information, including BOXED WARNING and Medication Guide or visit [Vafseo.com](http://Vafseo.com).**

For adults with anemia caused by CKD who have been on dialysis for at least 3 months

# Things to remember when taking Vafseo® (vadadustat)

## Before starting Vafseo

- Your doctor will run necessary blood tests to identify other reasons for anemia, check your Hb levels, iron levels, and check the health of your liver\*
- Tell your doctor about all of your medical conditions and medications that you take; please see Important Safety Information on page 7 for a list of conditions and medications that can affect how Vafseo works

## Starting treatment with Vafseo



Take once-a-day,  
orally (by mouth)



Take at a time that works for  
you, as directed by your doctor



Take separately from oral  
iron or phosphate binders

To reach and stay within your recommended Hb range, your doctor may need to adjust your dose or temporarily pause your Vafseo treatment if your Hb is too high or too low

\*Your doctor will do blood liver tests before starting treatment with VAFSEO, monthly for the first 6 months, and then as needed.

## IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat) (cont.)

### WARNINGS (cont.)

**High blood pressure.** VAFSEO may cause you to develop new or worsening high blood pressure. Monitor your blood pressure regularly, follow any instructions from your healthcare provider about controlling your blood pressure, and tell your healthcare provider about any changes.

**Seizures.** Seizures have happened in people treated with VAFSEO. Tell your healthcare provider about new onset of seizures, change in how often you have seizures, or if you experience signs or symptoms that a seizure may happen: headache, irritability, fear, confusion, or unusual feelings.

**Damage to the lining of the esophagus, stomach, or intestines (such as ulcers).** Your risk of damage to the lining of the esophagus, stomach, or intestines may increase if you have a prior history, stomach ulcers (peptic ulcer disease), use certain medicines that increase the risk of damage, or currently smoke tobacco or drink alcohol. Get medical care right away if you experience stomach-area (abdominal) discomfort or pain; nausea or vomiting; blood in your vomit or stool; black, tarry stools; trouble swallowing; pain in your throat or chest.

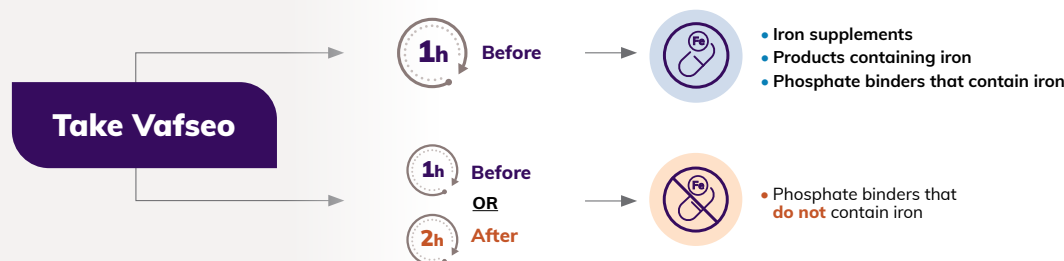
**Cancer.** Cancers have happened in people treated with VAFSEO. Talk to your healthcare provider if you have any concerns about cancer.

Please see additional Important Safety Information throughout, and on page 7.  
Please [click here](#) for the Full Prescribing Information, including BOXED WARNING and Medication Guide or visit [Vafseo.com](https://www.vafseo.com).

For adults with anemia caused by CKD who have been on dialysis for at least 3 months

# Your role in treatment: A guide to using Vafseo® (vadadustat)

- 1** Vafseo should be swallowed whole. It should not be cut, crushed, or chewed
- 2** To ensure Vafseo works properly, avoid taking it at the same time as iron supplements, products containing iron, or phosphate binders



- 3** You can take Vafseo with or without food
- 4** Missed a Vafseo dose? Take it when you remember on the same day. Continue with your usual schedule the next day
- 5** Do not take more than one dose a day. Tell your healthcare provider right away if you take more than your prescribed dose of Vafseo

## Continuing treatment with Vafseo

- You and your healthcare team will work together on getting to the right dose of Vafseo for you
- Your doctor will continue to run blood tests to ensure Vafseo is working safely and effectively (blood tests include measuring Hb levels, iron levels, and liver function)

## IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat) (cont.)

### WARNINGS (cont.)

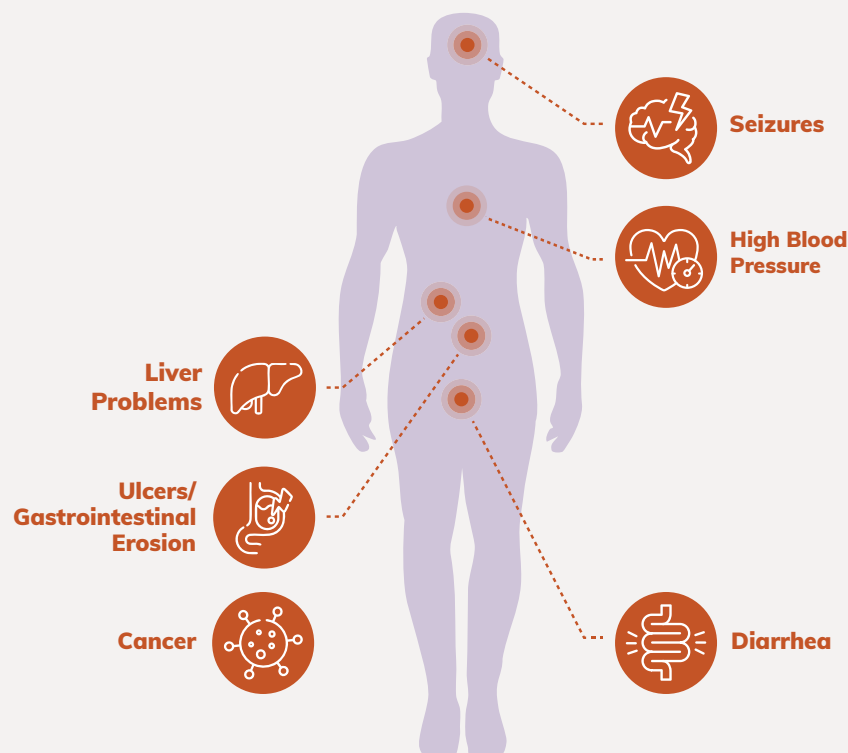
Ask a healthcare provider before use if you:

- have heart disease
- have had a stroke
- have liver problems
- have high blood pressure
- have had a seizure
- have a history of damage, such as ulcers, to the lining of the esophagus, stomach, or intestine
- smoke tobacco or drink alcohol
- have cancer
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed. Do not breastfeed during treatment with VAFSEO and for 2 days after your final dose

Please see additional Important Safety Information throughout, and on page 7. Please [click here](#) for the Full Prescribing Information, including BOXED WARNING and Medication Guide or visit [Vafseo.com](https://www.vafseo.com).

For adults with anemia caused by CKD who have been on dialysis for at least 3 months

## What are the possible side effects of Vafseo® (vadadustat)?



Vafseo may cause serious side effects including an increased risk of:

- Death
- Heart attack
- Stroke
- Blood clots

Call your healthcare provider for medical advice about any side effects. You may report suspected side effects to Akebia Therapeutics, Inc. at **1-844-445-3799** or the FDA at **1-800-FDA-1088** or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**Talk to your healthcare team about treatment with Vafseo**

### IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat) (cont.)

#### WARNINGS (cont.)

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take iron supplements, products containing iron or phosphate binders by mouth. These products affect how VAFSEO works and should not be taken at the same time you take VAFSEO. Ask your healthcare provider if you are not sure if you take any of these products.

#### WHEN USING VAFSEO, YOU MAY HAVE

- high blood pressure
- diarrhea

**Please see additional Important Safety Information throughout, and on page 7.**  
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## APPROVED USE

VPFSEO (vadadustat) is a prescription medicine used to treat anemia caused by chronic kidney disease (CKD) in adults who have been on dialysis for at least three months.

VPFSEO has not been proven to improve quality of life, tiredness (fatigue), or well-being.

### VPFSEO should not be used:

- in place of emergency treatment for anemia (red blood cell transfusions)
- for the treatment of anemia that is caused by CKD in people who are not on dialysis

## IMPORTANT SAFETY INFORMATION about VPFSEO (vadadustat)

### MOST IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT VPFSEO

#### VPFSEO may cause serious side effects, including:

**Increased risk of death, heart attack, stroke, and blood clots.** These risks may happen if you are treated with VPFSEO to increase red blood cells (RBCs) to near the same level found in healthy people. These risks may be increased if you have heart or blood vessel problems, or problems with blood flow to your brain. Blood clots can form in the blood vessels, including your legs, lungs, and in your dialysis access.

**Get medical help right away if you get any of the following signs or symptoms:** chest pain; trouble breathing or shortness of breath; cold sweat; sudden numbness or weakness in your face, arm or leg, especially on one side of your body; sudden confusion, trouble speaking, or trouble understanding others' speech; sudden trouble seeing; sudden trouble walking, dizziness, loss of balance or coordination; loss of consciousness (fainting); severe headache; pain in your legs, with or without swelling; a cool or pale arm or leg; changes to your dialysis access site, including swelling or discoloration near the site; do not feel a vibration ("thrill") over the dialysis access area.

If you decide to take VPFSEO, your healthcare provider should prescribe the lowest dose of VPFSEO that is necessary to reduce your chance of needing red blood cell transfusions.

#### DO NOT USE VPFSEO IF YOU:

- are allergic to vadadustat or any of the ingredients in VPFSEO. Refer to the Medication Guide for a complete list of ingredients in VPFSEO.
- have high blood pressure that is not controlled (uncontrolled hypertension).

## WARNINGS

#### VPFSEO may cause other serious side effects, including:

**Liver problems.** VPFSEO may cause changes in blood liver tests, which may be a sign of liver injury. Your healthcare provider will do blood liver tests before starting treatment with VPFSEO, monthly for the first 6 months and then as needed. Your healthcare provider may stop treatment with VPFSEO if you have changes in your blood liver tests. Tell your healthcare provider if you experience: tiredness; loss of appetite; pain in your right upper stomach area (abdomen); dark urine; yellowing of your skin or the white part of your eyes.

**High blood pressure.** VPFSEO may cause you to develop new or worsening high blood pressure. Monitor your blood pressure regularly, follow any instructions from your healthcare provider about controlling your blood pressure, and tell your healthcare provider about any changes.

**Seizures.** Seizures have happened in people treated with VPFSEO. Tell your healthcare provider about new onset of seizures, change in how often you have seizures, or if you experience signs or symptoms that a seizure may happen: headache, irritability, fear, confusion, or unusual feelings.

**Damage to the lining of the esophagus, stomach, or intestines (such as ulcers).** Your risk of damage to the lining of the esophagus, stomach, or intestines may increase if you have a prior history, stomach ulcers (peptic ulcer disease), use certain medicines that increase the risk of damage, or currently smoke tobacco or drink alcohol. Get medical care right away if you experience stomach-area (abdominal) discomfort or pain; nausea or vomiting; blood in your vomit or stool; black, tarry stools; trouble swallowing; pain in your throat or chest.

**Cancer.** Cancers have happened in people treated with VPFSEO. Talk to your healthcare provider if you have any concerns about cancer.

#### Ask a healthcare provider before use if you:

- have heart disease
- have had a stroke
- have liver problems
- have high blood pressure
- have had a seizure
- have a history of damage, such as ulcers, to the lining of the esophagus, stomach, or intestine
- smoke tobacco or drink alcohol
- have cancer
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed. Do not breastfeed during treatment with VPFSEO and for 2 days after your final dose

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take iron supplements, products containing iron or phosphate binders by mouth. These products affect how VPFSEO works and should not be taken at the same time you take VPFSEO. Ask your healthcare provider if you are not sure if you take any of these products.

#### WHEN USING VPFSEO, YOU MAY HAVE

- high blood pressure
- diarrhea

The risk information provided here is not complete. To learn more, talk about VPFSEO with your healthcare provider. The FDA-approved product labeling, including BOXED WARNING and Medication Guide, can be found [here](#).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch, or call 1-800-FDA-1088.



For adults with anemia caused by CKD who have been on dialysis for at least 3 months

# Vafseo® (vadadustat) is a once-daily pill that helps you manage your anemia every day.\*

## And it's not an injection.

- Taking Vafseo once-daily and keeping regular check-ins with your healthcare team are key to managing anemia together
- You and your doctor should talk about the possible health risks of Vafseo. Vafseo may cause serious health side effects, including risk of death, heart attack, stroke, and blood clots

Not an actual patient.

**Talk with your doctor about Vafseo and if managing your anemia caused by CKD with a once-a-day pill is right for you**



**To learn more about Vafseo and for helpful resources, scan here**

**The information in this brochure is not a substitute for advice from your healthcare team.**

\*Number of Vafseo pills per day will be dependent on your dose.



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