

Consumer Medicine Information (CMI) summary

See the [full CMI](#) on the following page for more information. If you have concerns about taking this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Vafseo?

Vafseo contains the active ingredient vadadustat. Vafseo is used to **treat anaemia** that is **associated with chronic kidney disease (CKD) in adults with chronic maintenance dialysis**. For more information, see Section [1. Why am I using Vafseo?](#) in the full CMI.

2. What should I know before I use Vafseo?

Do not use if you have ever had an allergic reaction to Vafseo or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use Vafseo?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Vafseo and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Vafseo?

- Always take Vafseo exactly as your doctor or pharmacist has told you.
- Vafseo should be taken once every day with food or between meals.
- Vafseo film-coated tablets are taken by mouth with water.
- Take your Vafseo tablet whole and without chewing or crushing the tablet.

More instructions can be found in Section [4. How do I use Vafseo?](#) in the full CMI.

5. What should I know while using Vafseo?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that you are using Vafseo. • Call your doctor straight away if you have headaches, especially sudden, stabbing, migraine-like headaches, bleeding from the nose, confusion, seizures or fits; pain in the chest or other parts of the body, feeling dizzy, shortness of breath or difficulty breathing, feeling nauseous or unwell, sense of anxiety, sweating or a cold sweat; speech difficulties, changes in your vision, numbness or weakness in the face, arms and legs on one side of the body, tingling of the extremities, dizziness, imbalance; coughing up blood; painful swelling and redness, usually in the leg; purplish, bulging veins seen through the skin, similar to varicose veins.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine without talking to your doctor. • Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tool until you know how Vafseo affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • Store below 30°C.

For more information, see Section [5. What should I know while using Vafseo?](#) in the full CMI.

6. Are there any side effects?

The most common side effects are high blood pressure, diarrhoea and blood clots. Serious side effects include high blood pressure, blood clots, heart attack, stroke, and blood clots in your dialysis access or fistula.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

VAFSEO®

Active ingredient(s): *vadadustat*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Vafseo. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Vafseo.**

Where to find information in this leaflet:

1. Why am I using Vafseo?

Vafseo contains the active ingredient vadadustat. Vafseo is a medicine that increases the amount of haemoglobin (the protein in your red blood cells that carries oxygen around the body) and the number of red blood cells in your blood.

Vafseo increases the level of a substance called “Hypoxia-Inducible Factor” (HIF), which increases the production of red blood cells when oxygen levels are low. By raising HIF levels, Vafseo increases the production of red blood cells and raises the levels of haemoglobin. This improves the oxygen supply to your body and may reduce your anaemia symptoms.

Vafseo is used to treat adults with anaemia (low levels of red blood cells or haemoglobin in your blood) that is associated with chronic kidney disease (CKD).

Vafseo is used to treat anaemia (low levels of red blood cells or haemoglobin in your blood) that is associated with chronic kidney disease (CKD) in adults on chronic maintenance dialysis. When the amount of haemoglobin or the number of red blood cells is low, the cells in your body might not receive enough oxygen. Anaemia can cause symptoms such as tiredness, weakness, or shortness of breath.

2. What should I know before I use Vafseo?

Warnings

Do not use Vafseo if:

- you are allergic to vadadustat, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions such as previous heart attack, stroke, blood clots, high blood pressure, liver disease, epilepsy or convulsions or risk factors so your doctor can decide if this medicine is a suitable treatment for your anaemia.

- take any medicines for any other condition or if you are converting from high doses of erythropoiesis-stimulating agent (ESA).
- Specific precautions relevant:
- if you had blood clots in the past and/or have risk factors for blood clots. This medicine increases the production of red blood cells and this may increase the risk of developing blood clots. Examples of risk factors are:
 - being overweight
 - diabetes
 - heart diseases
 - being off your feet for a long time because of surgery or illness
 - taking oral contraceptives
- Talk to your doctor immediately if you think you have developed a blood clot. You can find a description of possible blood clot symptoms in section 6.
- if you have high blood pressure (hypertension), Vafseo may worsen your high blood pressure. Therefore, it is very important that you take your high blood pressure medicines regularly and that you frequently check your blood pressure.
- if you have severe liver disease.
- if you have convulsion or fit or possible warning signs that a convulsion may occur, such as headache, irritability, fear, confusion or unusual feelings.
- if you are converting from high doses of erythropoiesis-stimulating agent (ESA) because you might require red blood cell transfusion or supplemental ESA while the doctor is adjusting your Vafseo dose.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant, think you may be pregnant, or intend to become pregnant, before taking this medicine.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether vadadustat passes into or is excreted in human milk.

Your doctor will decide whether you can take Vafseo during pregnancy or breast feeding.

It is not known if Vafseo has an effect on your fertility.

Cardiovascular Health

Chronic kidney disease can cause anaemia, which may increase the risk of heart and blood vessels problems and even death. Therefore it is important to treat your anaemia. Your doctor will regularly check the amount of haemoglobin in your blood.

Liver problems

The treatment may increase liver enzymes. Your doctor will regularly check the amount of these enzymes in your blood at the start of your treatment and then monthly for the first 3 months of your treatment and then as needed.

Use in Children

Do not give Vafseo to children and adolescents aged under 18 years. There is not enough information about its use in this age group.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Vafseo and affect how it works.

In particular, tell your doctor or pharmacist if you have taken, or are taking any of the following medicines:

- medicines to reduce phosphate levels in your blood (called phosphate binders) such as sevelamer carbonate or calcium acetate and medicines or supplements that contain iron such as ferric citrate, sucroferric oxyhydroxide, ferrous sulphate, sodium ferrous citrate,
- probenecid, a medicine used to treat gout,
- sulfasalazine, a medicine to treat severe bowel and rheumatic joint inflammation,
- medicines known as statins to reduce cholesterol levels in your blood (examples include simvastatin, rosuvastatin, fluvastatin or pitavastatin), furosemide or olmesartan, medicines used to treat high blood pressure,
- nelfinavir, efavirenz or zidovudine, medicines used to treat HIV,
- topotecan, a medicine used to treat cancer,
- famotidine, a medicine to treat stomach ulcers,
- methotrexate, a medicine used to treat cancer and autoimmune disorders,
- sitagliptin, a medicine to treat diabetes,
- celecoxib, a medicine to treat pain and inflammation,
- warfarin, a medicine used to stop blood clotting,
- phenytoin, a medicine used to treat epilepsy,
- benzylpenicillin, a medicine used to treat infections,
- teriflunomide, a medicine used to treat multiple sclerosis,
- p-aminohippuric acid, a diagnostic substance used in tests involving the kidney,
- bupropion, a medicine used to treat depression.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Vafseo.

4. How do I use Vafseo?

How much to take / use

- Your doctor will tell you what dose of Vafseo to take. Treatment with Vafseo will start at a daily dose of 300 mg. Thereafter, your doctor may either increase or decrease your daily dose in steps of 150 mg. The lowest dose is 150 mg per day and the highest dose is 600 mg per day.
- Always take Vafseo exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- It is important that your doctor regularly checks the amount of haemoglobin in your blood. Based on these test results your doctor may increase or lower your dose.
- If the amount of haemoglobin in your blood becomes too high your treatment will be stopped. Do not restart your treatment until your doctor tells you to do so and use only the dose your doctor prescribes. Your doctor will monitor your liver enzyme levels (ALT, AST, and bilirubin) before your treatment starts, and monthly thereafter for at least 3 months.
- Follow the instructions provided and use Vafseo until your doctor tells you to stop.

When to take / use Vafseo

- Vafseo should be taken once every day.
- Vafseo can be taken with food or between meals.
- Vafseo film-coated tablets are taken by mouth with water.
- Take your Vafseo tablet whole and without chewing or crushing the tablet.
- You can take Vafseo at any time before, during, or after dialysis.
- If you are treated with phosphate binders which do not include iron (such as sevelamer carbonate or calcium acetate) or medicines containing calcium, magnesium or aluminium you should take Vafseo at least 1 hour before or 2 hours after taking those medicines because, otherwise vadadustat will not be properly absorbed by your body. If the phosphate binder you are taking contains iron, see the information below.
- If you take medicines containing iron or phosphate binders containing iron you should take Vafseo at least 1 hour before those products. Vadadustat will not be properly absorbed by your body if you do not follow these instructions.

If you forget to use Vafseo

Vafseo should be used regularly at the same time each day. If you missed your dose at the usual time, take the missed dose during the same day as soon as you remember and take the next dose at the usual time the next day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed. Do not take two tablets on one day.

Take the forgotten dose as soon as possible and take the next dose on the next scheduled day. If you do not remember that you have missed a dose until the next day, skip the missed dose and take the next dose. If you stop taking Vafseo, your anaemia may get worse. Do not stop taking this medicine unless your doctor tells you to do so. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you use too much Vafseo

If you think that you have used too much Vafseo, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Vafseo?

Things you should do

Call your doctor straight away if you get any of the following:

- Signs and symptoms of high blood pressure (hypertension)
 - headaches, especially sudden, stabbing, migraine-like headaches.
 - bleeding from the nose.
 - confusion.
 - seizures or fits.
- Blood clots (thromboembolic events) which may lead to:
 - heart attack (myocardial infarction), with symptoms such as pain in chest and/or other parts of the body, feeling dizzy, shortness of breath, feeling nauseous or unwell, sense of anxiety, experience sweating or a cold sweat.
 - stroke (cerebrovascular accident), with symptoms such as speech difficulties, changes in your vision, numbness or weakness in the face, arms and legs on one side of the body, tingling of the extremities, dizziness, imbalance, sudden severe headache, seizures (fits).
 - blood clot in a blood vessel in the lungs (pulmonary embolism), with symptoms such as pain in your chest or upper back, difficulty breathing, coughing up blood.

- blood clot in a vein, such as in the leg (known as deep vein thrombosis), with symptoms such as painful swelling and redness.
- blood clots in your dialysis access, or fistula. Symptoms of a blocked fistula may be purplish, bulging veins seen through the skin, similar to varicose veins.

Remind any doctor, dentist or pharmacist you visit that you are using Vafseo.

Things you should not do

- Do not stop using this medicine without talking to your doctor.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Vafseo affects you.

Vafseo is unlikely to affect your ability to drive and use machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

This medicine does not require any special storage conditions.

Store below 30°C.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do **not** store it:

- in the bathroom or near a sink, or in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
<p>Signs and symptoms of high blood pressure:</p> <ul style="list-style-type: none"> headaches, especially sudden, stabbing, migraine-like headaches bleeding from the nose confusion seizures or fits <p>Blood vessel related:</p> <ul style="list-style-type: none"> blood clots which may lead to: <ul style="list-style-type: none"> heart attack, with symptoms such as pain in chest and/or other parts of the body, feeling dizzy, shortness of breath or difficulty breathing, feeling nauseous or unwell, sense of anxiety, sweating or a cold sweat stroke, with symptoms such as speech difficulties, changes in your vision, numbness or weakness in the face, arms and legs on one side of the body, tingling of the extremities, dizziness, imbalance, sudden severe headache, seizures (fits) blood clot in a blood vessel in the lungs, with symptoms such as pain in your chest or upper back, difficulty breathing, coughing up blood blood clot in a vein, such as in the leg, with symptoms such as painful swelling and redness blood clots in your dialysis access, or fistula. Symptoms of a blocked fistula may be purplish, bulging veins seen through the skin, similar to varicose veins <p>Nervous system related</p> <ul style="list-style-type: none"> seizures 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Less serious side effects

Less serious side effects	What to do
<p>Blood vessel related:</p> <ul style="list-style-type: none"> low blood pressure <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> diarrhoea constipation feeling sick vomiting <p>Infections related:</p> <ul style="list-style-type: none"> cold infection of the lung infection of the urinary tract fever, chills or any other symptoms of infection including with the bloodstream <p>Investigations related:</p> <ul style="list-style-type: none"> elevated liver enzymes increased amount of a breakdown product of red blood cells (bilirubin) in your blood <p>Pain related</p> <ul style="list-style-type: none"> headache pain in shoulders, neck, wrists, legs, and/or arms (pain in extremity) back pain <p>Complications related</p> <ul style="list-style-type: none"> fall dialysis related complication <p>Metabolism related</p> <ul style="list-style-type: none"> increased fluid in the body increased blood potassium <p>Cardiac related</p> <ul style="list-style-type: none"> irregular heart beat faster heart beat <p>Respiratory related</p> <ul style="list-style-type: none"> cough shortness of breath 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

This leaflet was prepared in September 2023.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Vafseo contains

Active ingredient (main ingredient)	vadadustat
Other ingredients (inactive ingredients)	<p>Tablet core</p> <ul style="list-style-type: none">• microcrystalline cellulose• sodium starch glycollate• hypromellose• silicon dioxide• magnesium stearate <p>Film-coating</p> <ul style="list-style-type: none">• Vafseo 150 mg - Opadry® II White 85F18422• Vafseo 300 mg - Opadry® II Yellow 85F12374• Vafseo 450 mg - Opadry® II Pink 85F94586

Do not take this medicine if you are allergic to any of these ingredients.

What Vafseo looks like

Vafseo 150 mg film-coated tablets are round and white, debossed with “VDT” on one side and “150” on the other side.

Vafseo 300 mg film-coated tablets are oval and yellow, debossed with “VDT” on one side and “300” on the other side.

Vafseo 450 mg film-coated tablets are oval and pink, debossed with “VDT” on one side and “450” on the other side.

(Aust R 384156 (150 mg), 384154 (300 mg) and 384152 (450 mg)).

Who distributes Vafseo

Adjutor Healthcare Pty Ltd
PO Box 6179
Point Cook VIC 3030
Australia