

## Package leaflet: Information for the patient

**Vafseo 150 mg film-coated tablets**

**Vafseo 300 mg film-coated tablets**

**Vafseo 450 mg film-coated tablets**

vadadustat

▼ 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. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What Vafseo is and what it is used for
2. What you need to know before you take Vafseo
3. How to take Vafseo
4. Possible side effects
5. How to store Vafseo
6. Contents of the pack and other information

#### 1. What Vafseo is and what it is used for

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. It contains the active substance vadadustat.

Vafseo is used to treat symptomatic 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.

#### How Vafseo works

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.

#### 2. What you need to know before you take Vafseo

##### Do not take Vafseo

- if you are allergic to vadadustat or any of the other ingredients of this medicine (listed in section 6).

## Warnings and precautions

Talk to your doctor, or pharmacist before taking Vafseo:

- 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 contraceptivesIt is important that you tell your doctor about previous heart attack, stroke, blood clots or risk factors so your doctor can decide if this medicine is a suitable treatment for your anaemia. Talk to your doctor immediately if you think you have developed a blood clot. You can find a description of possible blood clot symptoms below in section 4.
- 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.

### *Blood tests*

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.

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, monthly for the first 3 months of your treatment and then as needed.

## Children and adolescents

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

## Other medicines and Vafseo

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Vafseo may affect the way other medicines work, and medicines may affect how Vafseo 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

Your doctor will decide how you should use these medicines during your treatment with Vafseo.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not known whether vadadustat passes into 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.

### **Driving and using machines**

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

### **Vafseo contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

## **3. How to take Vafseo**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you what dose of Vafseo to take.

Your doctor will check your haemoglobin levels regularly and increase or lower your Vafseo dose based on your haemoglobin levels.

Vafseo is taken by mouth as film-coated tablets.

### **Taking Vafseo**

- Take your Vafseo dose 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

#### *Phosphate binders and Vafseo*

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.

#### *Iron containing products and Vafseo*

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.

## **Dosing Schedule**

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 as prescribed by your doctor.

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.

### **If you take more Vafseo than you should**

If you take more tablets or a higher dose than you should, contact your doctor straight away.

### **If you forget to take Vafseo**

- Do not take a double dose to make up for a forgotten dose. Do not take more than one dose in 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**

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.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **Possible serious side effects**

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

#### **Very common (may affect more than 1 in 10 people)**

- High blood pressure (hypertension)
- 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 or being sick, sense of anxiety
  - stroke (cerebrovascular accident), with symptoms such as sudden severe headache, seizures (fits), loss of coordination, loss of balance
  - 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
  - “mini stroke” (TIA), with symptoms such as speech and visual disturbance, and numbness or weakness in the face, arms and legs
  - stenosis (arteriovenous fistula thrombosis and arteriovenous graft thrombosis), with symptoms such as purplish, bulging veins seen through the skin, similar to varicose veins.

### **Other possible side effects**

Talk to your doctor if you get any of the following side effects:

#### **Very common (may affect more than 1 in 10 people)**

- diarrhoea

#### **Common (may affect up to 1 in 10 people):**

- headache
- seizures
- low blood pressure (hypotension)
- hypersensitivity
- cough
- constipation
- feeling sick
- vomiting
- increased liver enzymes

#### **Uncommon (may affect up to 1 in 100 people):**

- increased amount of a breakdown product of red blood cells (bilirubin) in your blood

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Vafseo**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater, or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Vafseo contains**

The active substance is vadadustat.

Vafseo 150 mg film-coated tablets:

- Each film-coated tablet contains 150 mg vadadustat.

Vafseo 300 mg film-coated tablets:

- Each film-coated tablet contains 300 mg vadadustat.

Vafseo 450 mg film-coated tablets

- Each film-coated tablet contains 450 mg vadadustat

The other ingredients are:

Tablet core

Microcrystalline cellulose, sodium starch glycolate, hypromellose, colloidal silicon dioxide, magnesium stearate.

Tablet coating:

Polyvinyl alcohol (E1203), macrogol (E 1521)/polyethylene glycol (PEG), talc.

*Vafseo 150 mg film-coated tablets*

Titanium dioxide

*Vafseo 300 mg film-coated tablets*

Titanium dioxide, yellow iron oxide

*Vafseo 450 mg film-coated tablets*

Titanium dioxide, iron oxide red and ferrousferrous oxide

**What Vafseo looks like and contents of the pack**

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.

Vafseo film-coated tablets are supplied in cartons containing 28 or 98 film-coated tablets in PVC/aluminium foil blisters.

**Marketing Authorisation Holder**

MEDICE Arzneimittel Pütter GmbH & Co. KG  
Kuhloweg 37  
58638 Iserlohn  
Germany

**Manufacturer**

Millmount Healthcare Limited  
Block-7, City North Business Campus,  
Stamullen, Co. Meath, K32 YD60  
Ireland

MEDICE Arzneimittel Pütter GmbH & Co. KG  
Kuhloweg 37  
58638 Iserlohn  
Germany

For any information about this medicine, please contact:  
MEDICE Arzneimittel Pütter GmbH & Co. KG  
Tel: +44 204 582 2845

**This leaflet was last revised in 04/2024**