

## PRESCRIBING INFORMATION

Vafseo<sup>®</sup>▼ (vadadustat) 150, 300 and 450mg film-coated tablets

Please refer to the Summary of Product Characteristics (SmPC) for further information before prescribing.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MEDICE UK on 020 4582 2845, [pv-uk@medice.co.uk](mailto:pv-uk@medice.co.uk)

Information about this product, including adverse reactions, precautions, contraindications, and method of use can be found at <https://www.medicines.org.uk/emc>.

**ACTIVE INGREDIENT:** Vadadustat

### INDICATION:

For the treatment of symptomatic anaemia associated with chronic kidney disease (CKD) in adults on chronic maintenance dialysis.

### DOSAGE and ADMINISTRATION:

The recommended starting dose is 300 mg once daily. Do not increase the dose more frequently than once every 4 weeks. Decreases in dose can occur more frequently.

### DOSE ADJUSTMENTS:

Dose adjustment should be done in increments of 150 mg within the range of 150 mg to a maximum recommended daily dose of 600 mg to achieve or maintain Haemoglobin (Hb) levels within 10 to 12 g/dL. For Hb levels >12 g/dL but less than 13 g/dL, reduce dose by 150 mg. Refer to SmPC for full information regarding Hb levels exceeding 13 g/dL or rapidly rising Hb whilst taking Vafseo. Treatment should not be continued beyond 24 weeks of therapy if a clinically meaningful increase in Hb levels is not achieved. Patients converting from an erythropoiesis-stimulating agent (ESA): When converting from an ESA to Vafseo, the recommended starting dose is 300 mg once daily. Those patients converting from a high baseline dose of ESA may experience an initial decline in Hb levels before gradually returning to baseline Hb levels by Weeks 16 to 20. Refer to SmPC for full information on converting from an ESA.

### ADMINISTRATION:

The film-coated tablet is administered orally with or without food and should be swallowed whole without chewing. Vafseo can be taken at any time before, during, or after dialysis.

### EVALUATION, MONITORING and ADMINISTRATION INSTRUCTIONS:

Evaluate the iron status in all patients before and during treatment and administer supplemental iron therapy when serum ferritin is < 100mcg/L or TSAT < 20%. When initiating or adjusting therapy, monitor Hb levels every 2 weeks until stable, then at least monthly. ALT, AST, and bilirubin must be evaluated prior to initiation, monthly for three months after initiation and as clinically indicated thereafter. Administer at least 1 hour before oral iron supplements, products whose primary component consists of iron, or iron- containing phosphate binders. Administer at least 1 hour before or 2 hours after non-iron- containing phosphate binders or other medicinal products whose primary component consists of multivalent cations such as calcium, magnesium or aluminium. If a dose is missed, patients should take the dose as soon as they remember during the same day and then take the next dose at the usual time the next day. Do not take a double dose.

### CONTRAINDICATIONS:

Hypersensitivity to the active substance or to any of the excipients.

**SPECIAL WARNINGS and PRECAUTIONS:**

Vafseo should not be administered in patients with non-dialysis dependent (NDD) CKD. Blood pressure should be monitored before initiation and regularly thereafter. Vascular Access Thrombosis (VAT) is a common occurrence in patients receiving haemodialysis and therefore patients with pre-existing risk factors for thromboembolic events and prior history of thromboembolic events should be monitored carefully. Patients with signs and symptoms of thromboembolic events, serious adverse cardiovascular reactions or stroke should be promptly evaluated and treated according to standard of care. The decision to interrupt or discontinue treatment should be based on a benefit-risk consideration for the individual patient. Vafseo is not recommended for use in patients with severe hepatic impairment (Child-Pugh class C). An increase in ALT, AST (frequency common) and/or bilirubin (frequency uncommon) attributed to Vafseo was reported. Discontinue if ALT or AST elevations > 3x Upper Limit of Normal (ULN) are accompanied by a bilirubin increase > 2x ULN, or if there is persistent ALT or AST > 3x ULN. Use with caution in patients with a history of seizures or fits, epilepsy or medical conditions associated with a predisposition to seizure activity such as central nervous system (CNS) infections. Blood pressure should be monitored before initiation and regularly thereafter and all patients should be advised to comply with antihypertensive therapy and blood pressure monitoring. Hb levels may initially decrease in patients converting from ESA to Vafseo. Rescue therapy such as RBC transfusion or ESA treatment may be considered if Hb fall below 9 g/dL or if response is not considered acceptable. Vafseo should be paused temporarily during ESA rescue treatment. This medicine contains less than 1 mmol sodium (23 mg) per dosage.

**INTERACTIONS:**

If co-administration with strong or moderate OAT1 or OAT3 inhibitors (e.g. benzylpenicillin, teriflunomide or p-aminohippuric acid) occurs, patients should be managed cautiously and evaluated for excessive effects of Vafseo. Dose adjustment of co-prescribed BCRP (i.e. sulfasalazine, simvastatin, rosuvastatin) or OAT3 substrates may be needed and monitor for excessive signs of co-administered BCRP substrates such as fluvastatin, nelfinavir, pitavastatin and topotecan, refer to SmPC for full information. Vafseo was an inducer of CYP2B6 in *in vitro* studies. Exercise caution when co-administering with CYP2B6/CYP3A4/CYP2C8 substrates and narrow therapeutic CYP2C9 substrates (i.e. warfarin), refer to SmPC for full information.

**FERTILITY, PREGNANCY and LACTATION:**

As a precautionary measure, Vafseo should only be used during pregnancy if the benefit justifies the potential risk to the foetus. A benefit-risk evaluation of the use during breastfeeding should be undertaken. There are no data on the potential impacts on fertility in humans.

**UNDESIRABLE EFFECTS:**

The most frequent adverse reactions in DD-CKD and NDD-CKD patients treated with Vafseo respectively were hypertension (11.1% / 16.0%), diarrhoea (12.7% / 13.0%) and thromboembolic events (13.7% / 6.9%). **Very Common:** Hypertension, thromboembolic events, diarrhoea. **Common:** Headache, seizures, hypotension, hypersensitivity, cough, constipation, nausea, vomiting, elevated liver enzymes. **Uncommon:** Blood bilirubin increased. Prescribers should consult the SmPC in relation to full side effect information. See *Special Warnings and precautions* for serious side effects.

**PHARMACEUTICAL PRECAUTIONS:**

This medicinal product does not require any special storage conditions.

**LEGAL CATEGORY:** POM.

Product	Marketing Authorisation Number	Package Quantities		List Price
Vafseo 150mg	PLGB 11243/0054	150 mg	28 tablets	£148.59
Vafseo 150mg		150 mg	98 tablets	£520.08
Vafseo 300mg	PLGB 11243/0055	300mg	28 tablets	£297.19
Vafseo 300mg		300mg	98 tablets	£1,040.16
Vafseo 450mg	PLGB 11243/0056	Not available at launch		
Vafseo 450mg		Not available at launch		

**MARKETING AUTHORISATION HOLDER:**

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

**Marketed in the UK** by MEDICE UK Ltd. Ground Floor, Unit B, The Chase, Foxholes Business Park,  
Hertford, Herts, SG13 7NN. Tel: 020 4582 2845. Email: [medicalinformation@medice.co.uk](mailto:medicalinformation@medice.co.uk)  
Note: Not all strengths and pack sizes are marketed in the UK.

Vafseo is a registered trademark of MEDICE Arzneimittel Pütter GmbH & Co. KG.

**DATE OF REVISION OF PRESCRIBING INFORMATION:** July 2025