Tavneos ®▼(avacopan)

Prescribing Information – Great Britain

For full prescribing information refer to the Summary of Product Characteristics (SmPC)

Active ingredient: Avacopan

Presentation: Hard capsules available as 10 mg.

Indication: Tavneos, in combination with a rituximab or cyclophosphamide regimen, is indicated for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA).

Dosage and Administration: Treatment should be initiated and monitored by healthcare professionals experienced in the diagnosis and treatment of GPA or MPA. The recommended dose is 30 mg taken orally twice daily, morning and evening, with food. Tavneos should be administered in combination with a rituximab or cyclophosphamide regimen as follows: rituximab for 4 weekly intravenous doses or, intravenous or oral cyclophosphamide for 13 or 14 weeks, followed by oral azathioprine or mycophenolate mofetil and, glucocorticoids as clinically indicated. If a patient misses a dose, the missed dose is to be taken as soon as possible, unless within three hours of the next scheduled dose. Treatment must be re-assessed clinically and temporarily stopped if: alanine aminotransferase (ALT) or aspartate aminotransferase (AST) is more than 3 times the upper limit of normal (ULN). Treatment must be temporarily stopped if: ALT or AST > 5 × ULN, a patient develops leukopenia, neutropenia, or lymphopenia, or a patient has an active, serious infection. Treatment may be resumed: upon normalisation of values and based on an individual benefit/risk assessment. Permanent discontinuation of treatment must be considered if: ALT or AST > 8 × ULN, ALT or AST > 5 × ULN for more than 2 weeks, ALT or AST > 3 × ULN and total bilirubin > 2 × ULN or international normalised ratio (INR) > 1.5, ALT or AST > 3 × ULN with the appearance of fatigue, nausea, vomiting, right upper quadrant pain or tenderness, fever, rash, and/or eosinophilia (> 5%), or an association between avacopan and hepatic dysfunction has been established.

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

Special warnings and precautions: Hepatic transaminases, total bilirubin, and white blood cell (WBC) count must be obtained prior to initiation of therapy and patients must be monitored for these as clinically indicated and as part of the routine follow-up of patient's underlying condition. In the post-marketing setting, drug-induced liver injury and vanishing bile duct syndrome (VBDS), including cases with fatal outcome, have been reported. Avacopan must be avoided in patients with signs of liver disease, such as elevated AST, ALT, alkaline phosphatase (ALP), or total bilirubin > 3 times ULN. Treatment with avacopan must not be initiated if WBC count is less than 3.5×10^9/L, or neutrophil count less than 1.5×10^9/L, or lymphocyte count less than 0.5×10^9/L. Patients must be assessed for any serious infections. Avacopan has not been studied in patients with hepatitis B, hepatitis C, or human immunodeficiency virus (HIV) infections. Be cautious when treating patients with a history of tuberculosis, hepatitis B, hepatitis C, or HIV infection. Monitor patients treated for ANCA-associated vasculitis according to standard practice for clinical signs and symptoms of *Neisseria* infection. *Pneumocystis jirovecii* pneumonia prophylaxis is recommended for adult patients with GPA or MPA during avacopan treatment, as appropriate according to local clinical practice guidelines. The safety of immunisation with live vaccines, following avacopan therapy has not been studied. Administer vaccinations preferably prior to initiation of treatment with avacopan or during quiescent phase of the disease. Angioedema has been reported in patients receiving avacopan and avacopan must be withheld in cases of angioedema. The use of strong CYP3A4 enzyme inducers with avacopan is to be avoided. Patients anticipated to require long-term administration of these medicinal products are not to be treated with avacopan. If short-term co-administration cannot be avoided in a patient already using avacopan, the patient must be closely monitored in case of any reoccurrence of disease activity. Patients with GPA or MPA are at risk of cardiac disorders such as myocardial infarction, cardiac failure, and cardiac vasculitis. A treatment regimen based on the combination with cyclophosphamide followed by azathioprine may carry an increased risk for cardiac disorders as compared to a regimen based on the combination with rituximab. Immunomodulatory medicinal products may increase the risk for malignancies. The clinical data are currently limited. This medicinal product contains macrogolglycerol hydroxystearate, which may cause stomach upset and diarrhoea.

Overdose: It is recommended that the patient is monitored for any signs or symptoms of adverse effects, and appropriate symptomatic treatment and supportive care are provided.

Special populations: No dose adjustment is required in elderly patients. No dose adjustment is needed based on renal function nor for patients with mild or moderate hepatic impairment. Avacopan has not been studied in subjects with severe hepatic impairment (Child-Pugh Class C) and it is therefore not recommended for use in these patient populations. Avacopan has not been studied in patients with anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis with an eGFR below 15 mL/min/1.73 m², who are on dialysis, in need of dialysis or plasma exchange, nor in patients with severe disease manifested as alveolar haemorrhage. The safety and efficacy of avacopan in children below 12 years of age and adolescents (12-17 years of age) have not yet been established. No data are available in children below 12 years of age. Avacopan is not recommended during pregnancy and in women of childbearing potential not using contraception. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from therapy with avacopan, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Undesirable effects: *Very common (≥ 1/10):* Upper respiratory tract infection, nasopharyngitis, headache, nausea, diarrhoea, vomiting, liver function test increased, WBC count decreased. *Common (≥ 1/100 to < 1/10):* pneumonia, rhinitis, urinary tract infection, sinusitis, bronchitis, gastroenteritis, lower respiratory tract infection, cellulitis, herpes zoster, influenza, oral candidiasis, oral herpes, otitis media, neutropenia, abdominal pain upper, blood creatine phosphokinase increased. *Uncommon (≥ 1/1,000 to < 1/100):* angioedema. *Not Known (frequency cannot be estimated from the available):* Drug-induced liver injury, vanishing bile duct syndrome.

The most common serious adverse reactions are liver function abnormalities (5.4%) and pneumonia (4.8%).

Please consult the SmPC for further information on undesirable effects.

Legal category: POM

List price: Pack of 180 x 10 mg hard capsules = £5,547.95

MA Number: PLGB 50784/0008

Date of Authorisation: 06/05/2022 (Great Britain)

MA Holder: Vifor Fresenius Medical Care Renal Pharma France, 100–101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France.

Tavneos® is a registered trademark

Document number: UK-AVA-2400122
Date of preparation: July 2024

▼ This medicine is subject to additional monitoring. Adverse events should be reported. Reporting forms and information for Great Britain (UK) can be found at https://yellowcard.mhra.gov.uk/
Adverse events should also be reported to Vifor Fresenius Medical Care Renal Pharma, care of Vifor Pharma Ltd.
Tel: +44 1276 853633. E-mail: MedicalInfo_UK@viforpharma.com

Tavneos ®▼(avacopan)

Prescribing Information – Northern Ireland

For full prescribing information refer to the Summary of Product Characteristics (SmPC)

Active ingredient: Avacopan

Presentation: Hard capsules available as 10 mg.

Indication: Tavneos, in combination with a rituximab or cyclophosphamide regimen, is indicated for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA).

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Legal category: POM

List price: Pack of 180 x 10 mg hard capsules = £5,547.95

MA Number: EU/1/21/1605/001, EU/1/21/1605/002

Date of Authorisation: 11/01/2022 (Northern Ireland)

MA Holder: Vifor Fresenius Medical Care Renal Pharma France, 100–101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France.

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Document number: UK-AVA-2400120
Date of preparation: July 2024

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Adverse events should also be reported to Vifor Fresenius Medical Care Renal Pharma, care of Vifor Pharma Ltd.
Tel: +44 1276 853633. E-mail: MedicalInfo_UK@viforpharma.com