TAVNEOS® (Avacopan): Abbreviated Prescribing Information

Tavneos 10 mg hard capsules. Each hard capsule contains 10 mg of avacopan.
Therapeutic Indications: 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). **Posology and Method of 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 Tavneos (3 hard capsules of 10 mg each) taken orally twice daily, morning and evening, with food. Grapefruit and grapefruit juice are to be avoided in patients treated with avacopan. Tavneos should be administered in combination with a rituximab or cyclophosphamide regimen (Please refer to the insert leaflet for full information). ***Missed doses:*** 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. If within three hours, then the missed dose is not to be taken. ***Dose management:*** 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) (Please refer to the insert leaflet for full information). **Special populations:** ***Elderly:*** No dose adjustment is required in elderly patients. ***Hepatic impairment***: No dose adjustment is required 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. ***Renal impairment:*** No dose adjustment is needed based on renal function. Avacopan has not been studied in patients with anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis with an estimated glomerular filtration rate (eGFR) below 15 mL/min/1.73 m^2, who are on dialysis, in need of dialysis or plasma exchange. ***Severe disease manifested as alveolar haemorrhage:*** Avacopan has not been studied in patients with severe disease manifested as alveolar haemorrhage. ***Paediatric population:*** The safety and efficacy of avacopan in children below 17 years of age. **Special warnings and precautions for use *(Please refer to the insert leaflet for full information)*: *Liver function test increased:*** Serious adverse reactions of elevated hepatic transaminases with elevated total bilirubin have been observed in patients receiving avacopan in combination with cyclophosphamide (followed by azathioprine or mycophenolate) or rituximab and trimethoprim and sulfamethoxazole. Liver function test (LFT) increased is considered as an adverse reaction. 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. Hepatic transaminases and total bilirubin must be obtained prior to initiation of therapy. ***Blood and immune system:*** Treatment with avacopan must not be initiated if WBC count is less than 3500/µL, or neutrophil count less than 1500/µL, or lymphocyte count less than 500/µL. ***Serious infections:*** have been reported in patients receiving combination agents for treatment of GPA or MPA, including avacopan in combination with rituximab or cyclophosphamide. 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. ***Angioedema:*** has been reported in patients receiving avacopan. Avacopan must be withheld in cases of angioedema. ***Interaction with strong CYP3A4 inducers:*** The use of strong CYP3A4 enzyme inducers (e.g., carbamazepine, enzalutamide, mitotane, phenobarbital, phenytoin, rifampicin, and St. John's Wort) with avacopan is to be avoided (for full information on interaction please refer to the insert leaflet). ***Cardiac disorders:*** Patients with GPA or MPA are at risk of cardiac disorders such as myocardial infarction, cardiac failure, and cardiac vasculitis. Serious adverse events (SAEs) of cardiac disorder have been reported in patients treated with avacopan. ***Fertility, pregnancy and lactation:*** There are no data from the use of avacopan in pregnant women. Avacopan is not recommended during pregnancy and in women of childbearing potential not using contraception. Avacopan has not been measured in milk of lactating animals. A risk to newborns/infants cannot be excluded. There are no data on the effects of avacopan on human fertility. ***Effects on ability to drive and use machines:*** Tavneos has no or negligible influence on the ability to drive and use machines. **Undesirable effects:** ***Summary of the safety profile*** (for full information on undesirable effects please refer to the insert leaflet): *The most common adverse reactions* are nausea (23.5%), headache (20.5%), white blood cell count decreased (18.7%), upper respiratory tract infection (14.5%), diarrhoea (15.1%), vomiting (15.1%), and nasopharyngitis (15.1%). *The most common serious adverse reactions* are liver function abnormalities (5.4%) and pneumonia (4.8%). **Overdose:** Avacopan was studied in healthy subjects at a maximum total daily dose of 200 mg (given as 100 mg twice daily) for 7 days without evidence of dose limiting toxicities. In case of an 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.

Legal category: POM
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For reporting the Adverse events, it should be reported to Vifor International AG Rep office
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