Prescribing Information: Cablivi (caplacizumab) 10 mg powder and solvent for solution for injection

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Each vial of powder contains 10 mg of caplacizumab. Each pre-filled syringe of solvent contains 1 ml of water for injections.

Indication: The treatment of adults and adolescents of 12 years of age and older weighing at least 40 kg experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), in conjunction with plasma exchange and immunosuppression.

Dosage and Administration: Treatment with Cablivi should be initiated and supervised by physicians experienced in the management of patients with thrombotic microangiopathies. First dose: Intravenous (IV) injection of 10 mg of caplacizumab prior to plasma exchange. Subsequent doses: Daily subcutaneous (SC) administration of 10 mg of caplacizumab, into the abdomen, after completion of each plasma exchange for the duration of daily plasma exchange treatment, followed by daily subcutaneous injection of 10 mg of caplacizumab for 30 days after stopping daily plasma exchange treatment. Injections into the area around the navel should be avoided and consecutive injections should not be administered in the same abdominal quadrant. Patients or caregivers may inject the medicinal product after proper training in the SC injection technique. If at the end of this 30 day period there is evidence of unresolved immunological disease, it is recommended to optimise the immunosuppression regimen and continue daily subcutaneous administration of 10 mg of caplacizumab until the signs of underlying immunological disease are resolved (e.g. sustained normalisation of ADAMTS13 activity level). In the clinical development program, caplacizumab has been administered daily for up to 71 days consecutively. Data on retreatment with caplacizumab are available. Missed dose: The first dose of caplacizumab should be administered IV before the initial plasma exchange. If the administration of the first IV dose of caplacizumab is missed and plasma exchange is already administered, the first caplacizumab dose should still be administered IV after the plasma exchange is complete and the next dose should be administered SC on the following day according to the usual dosing schedule. If a dose of Cablivi is missed, it can be administered within 12 hours. If ≥12 hours have passed since the dose was to have been given, the missed dose should not be administered and the next dose should be administered per the usual dosing schedule.

Special Populations: Renal impairment and mild-moderate hepatic impairment: No dose adjustment necessary. Severe hepatic impairment: No data available in patients with severe acute or chronic hepatic impairment. Use of Cablivi in this population requires a benefit/risk assessment and close clinical monitoring. Elderly: Experience in the elderly is limited, however there is no evidence to suggest that dose adjustment or special precautions are necessary. Paediatric population: The safety and efficacy of caplacizumab in the paediatric population have not been established in clinical studies. The posology of Cablivi in adolescents of 12 years of age and older weighing at least 40 kg is the same as in adults. No recommendations can be made on the posology of Cablivi for paediatric patients below 40 kg of body weight.

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

Warnings and Precautions: Bleeding: Cablivi increases the risk of bleeding. Cases of major bleeding, including life-threatening and fatal bleeding have been reported in patients receiving caplacizumab, mainly in those using concomitant anti-platelet agents or anticoagulants. Caplacizumab should be used with caution in patients with underlying conditions that may predispose them to a higher risk of bleeding. In case of clinically significant bleeding, treatment with Cablivi should be interrupted. If needed, the use of von Willebrand Factor concentrate could be considered to correct haemostasis. Cablivi should only be restarted upon the advice of a physician experienced in the management of thrombotic microangiopathies. If Cablivi is restarted, monitor closely for signs of bleeding. *In the setting of concomitant use of oral anticoagulants, anti-platelet agents, thrombolytic agents or heparin:* The risk of bleeding is increased with concomitant use of Cablivi with other medicinal products affecting haemostasis and coagulation. Initiation or continuation of treatment with oral anti-coagulants (e.g. vitamin K antagonists or direct oral anticoagulants [DOAC] such as thrombin inhibitors or factor Xa inhibitors), anti-platelet agents, thrombolytic agents such as urokinase, tissue plasminogen activator (t-PA) (e.g. alteplase) or heparin requires careful consideration and close clinical monitoring. *In patients with coagulopathies (e.g. hemophilia, other coagulation factor deficiencies):* Due to a potential increased risk of bleeding, use of Cablivi in these patients must be accompanied by close clinical monitoring. *In patients undergoing surgery:* If a patient is to undergo elective surgery, an invasive dental procedure or other invasive interventions, the patient must be advised to inform the physician or dentist that they are using caplacizumab, and it recommended to withhold treatment for at least 7 days before the planned intervention. The patient must also notify the physician who supervises the treatment with caplacizumab about the planned procedure. After the risk of surgical bleeding has resolved and caplacizumab is resumed, the patient should be monitored closely for signs of bleeding. If emergency surgery is needed, the use of von Willebrand Factor concentrate is recommended to correct haemostasis. Excipient: This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium-free”.

Interactions: No interaction studies evaluating use of caplacizumab with oral anticoagulants (e.g. vitamin K antagonists, direct oral anticoagulants [DOAC] such as thrombin inhibitors or factor Xa inhibitors), antiplatelet agents, thrombolytic agents such as urokinase, tPA (e.g. alteplase) or heparin have been performed.

Fertility, pregnancy and lactation: There are no data on the use of caplacizumab in pregnant or breast-feeding women. As a precautionary measure, it is preferable to avoid the use of Cablivi during pregnancy. It is unknown whether caplacizumab is excreted in human milk, risk to the child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to abstain/discontinue from therapy, considering the benefit of breastfeeding for the child and the benefit of therapy for the woman.

Adverse Reactions: Very common: headache, epistaxis, gingival bleeding, urticaria, pyrexia and fatigue. Common: cerebral infarction, haematoma, dyspnoea, haemoptysis, haematemesis, haematochezia, melaena, haemorrhage (eye, upper gastrointestinal, haemorrhoidal, rectal, vaginal, subarachnoid), abdominal wall haematoma, myalgia, haematuria, menorrhagia, injection site reaction

(haemorrhage, pruritus, erythema, pain, bruising). *Prescribers should consult the SmPC in relation to other adverse reactions.*
List price: 1 vial: £4,143; 7 vials £29,000.
Legal Category: POM.
Marketing Authorisation Number: PLGB 04425/0888.
Marketing Authorisation Holder: Sanofi, 410 Thames Valley Park Drive, Reading Berkshire, RG6 1PT, UK.

Further information is available from: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902314. Alternatively, send via email to UK-drugsafety@sanofi.com