UAE – Oman –Qatar- Kuwait

Caplacizumab - Abbreviate Prescribing Information (API)

Name and Presentation: Caplacizumab 10 mg powder and solvent for solution for injection. Each vial of powder contains 10 mg of caplacizumab. Each pre-filled syringe of solvent contains 1 mL of water for injections. Caplacizumab is a humanised bivalent Nanobody produced in Escherichia coli by recombinant DNA technology. **Therapeutic indications:** Cablivi is indicated for 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. **Posology and method of administration**: Treatment with Cablivi should be initiated and supervised by physicians experienced in the management of patients with thrombotic microangiopathies. **Posology:** The first dose is an intravenous injection of 10 mg of caplacizumab prior to plasma exchange. Subsequent daily doses of 10 mg of caplacizumab are administrated subcutaneously after completion of each plasma exchange during the daily plasma exchange treatment and 30 days after stopping the daily plasma exchange treatment. If at the end of this period there is evidence of unresolved immunological disease, it is recommended to optimise the immunosupression regimen and continue the 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). Special populations: No dose adjustment is necessary for patients with renal impairment or with hepatic impairment. The safety and efficacy of caplacizumab in the paediatric population have not yet been established. **Method of administration:** The first dose of Cablivi is to be administered as an intravenous injection. Subsequent doses are to be administered via subcutaneous injection in the abdomen. Injections into the area around the navel should be avoided and consecutive injections should not be administered in the same abdominal quadrant. **Contraindications:** hypersensitivity to the active substance or to any of the excipients. See full SmPC for full list of exipients. **Warnings and precautions:** In case of active, clinically significant bleeding, Cablivi should be interrupted. If needed, the use of von Willebrand Factor concentrate could be considered to correct hemostasis. Cablivi should only be restarted upon the advice of a physician experienced in the management of thrombotic microangiopathies. Due to a potential increased risk of bleeding, initiation or continuation of treatment with oral anticoagulants or high dose heparin requires a benefit/risk assessment and close clinical monitoring. While no increased risk of bleeding was observed in clinical trials, concomitant treatment with anti-platelet agents and/or low molecular weight heparin requires a benefit/risk assessment and close clinical monitoring. Patients with underlying coagulopathies should be closely clinically monitored. If a patient is to undergo elective surgery or a dental procedure, the patient should be advised to inform the physician or dentist that they are using Cablivi, and treatment should be stopped at least 7 days before the planned intervention. The patient should also notify the physician who supervises the treatment with Cablivi about the planned procedure. If emergency surgery is needed, the use of von Willebrand Factor concentrate could be considered to correct hemostasis. No data on the use of Cablivi in patients with severe acute or chronic hepatic impairment are available and use of Cablivi in this population requires a benefit/risk assessment and close clinical monitoring. **Drug interactions:** No formal drug interaction studies have been conducted**. Fertility, pregnancy and lactation:** No data on the use of Cablivi in pregnant women are available. 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 and a risk to the child cannot be excluded. A decision must be made whether to discontinue breastfeeding or to abstain/discontinue from therapy, taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman. **Effects on ability to drive:** Cablivi has no or negligible influence on the ability to drive and use machines.

Undesirable effects: The most frequent adverse reactions in clinical trials were epistaxis, headache and gingival bleeding. The most common serious adverse reaction was epistaxis. In clinical studies, bleeding events occurred in different body systems, independent of treatment duration. Although in some cases these events were serious and required medical attention, most were self-limited and all resolved. In case of active clinically significant bleeding, consider actions outlined in sections Warning and Precautions and Overdose. *Nervous system disorders:* very common: headache; common: cerebral infarction. *Eye disorders:* common: eye haemorrhage. *Vascular disorders:* common: haematoma. *Respiratory, thoracic and mediastinal disorders:* very common: epistaxis; common: dyspnoea, haemoptysis. *Gastrointestinal disorders:* very common: Gingival bleeding; common: haematemesis, haematochezia, melaena, upper gastrointestinal haemorrhage, haemorrhoidal haemorrhage, rectal haemorrhage, abdominal wall haematoma. *Skin and subcutaneous tissue disorders:* very common: urticaria. *Musculoskeletal and connective tissue disorders*: common: myalgia. *Renal And Urinary Disorders:* common: haematuria. *Reproductive system and breast disorders:* common: menorrhagia, vaginal haemorrhage. *General disorders and administration site conditions*: very common: pyrexia, fatigue; common: injection site haemorrhage, injection site pruritus, injection site erythema, injection site reaction. *Injury, Poisoning and Procedural Complications:* common: subarachnoid haemorrhage. **Overdose:** Based on the pharmacological action of caplacizumab, there is the potential for an increased risk of bleeding. Close monitoring for signs and symptoms of bleeding is recommended (see Precautions and Warnings). **Special precautions for storage:** Store in a refrigerator (2 °C - 8 °C).Do not freeze. Store in the original package in order to protect from light. Cablivi may be stored at a temperature not above 25 °C for a single period of up to 2 months. Do not return Cablivi to refrigerated storage after storage at room temperature. **Pharmacological properties:** *Pharmacotherapeutic group:* Other antithrombotic agents, *ATC code:* B01AX07. Caplacizumab is a humanised bivalent Nanobody targeting the A1-domain of von Willebrand factor and inhibiting the interaction between von Willebrand factor and platelets. *Marketing authorization holder:* Ablynx NV, Technologiepark 21- 9052 Zwijnaarde- Belgium. Medicinal product subject to restricted medical prescription. Before prescribing always refer to full SmPC. **Date:** Reviewed April 2023. Before prescribing always refer to your full local prescribing information as this information may vary from country to country.
This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

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KSA

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For all Gulf Countries: +971 565776791 or
e-mail: medical-information.gulf@sanofi.com
To report an adverse event or drug reaction, please contact us on:
24/ 7 Pharmacovigilance reporting number: +971 561747001 e-mail:
gulf.pharmacovigilance@sanofi.com
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