Starting your patient on CABLIVI

Dosing and administration



Initiate CABLIVI in combination with PEX and continue for at least 30 days after last daily PEX



INITIATE CABLIVI

ON DAY 1, USE IV AND SC

11-mg bolus IV injection at least

Followed by an 11-mg SC injection

15 minutes prior to PEX

after completed PEX

2. ADMINISTER DURING PEX

DAILY DURING PEX

Daily 11-mg SC injection following completion of daily PEX

3. ADMINISTER

DAILY FOR 30 DAYS

Daily 11-mg SC injection for 30 days after

TREATMENT EXTENSION (UP TO 28 DAYS IF NEEDED)

Daily 11-mg SC injection after initial treatment if signs of underlying disease persist (such as suppressed ADAMTS13)

MISSED DOSE DURING PEX

 If a dose of CABLIVI is missed during the PEX period, it should be given as soon as possible

MISSED DOSE AFTER PEX

- If a dose of CABLIVI is missed after the PEX period, it can be administered within 12 hours of the scheduled time of administration
- Beyond 12 hours, the missed dose should be skipped and the next daily dose administered according to the usual dosing schedule

Discontinue CABLIVI if the patient experiences >2 recurrences of aTTP while on CABLIVI.

Withhold CABLIVI treatment 7 days prior to elective surgery, dental procedures, or other invasive interventions.

Avoid concomitant use of antiplatelet agents or anticoagulants.

PEX = Plasma exchange aTTP = acquired thrombotic thrombocytopenic IV=intravenous; SC=subcutaneous.

INDICATIONS:

CABLIVI (caplacizumab-yhdp) is indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

CABLIVI is contraindicated in patients with a previous severe hypersensitivity reaction to caplacizumab-yhdp or to any of its excipients. Hypersensitivity reactions have included urticaria.

WARNINGS AND PRECAUTIONS:

Hemorrhage:

 CABLIVI increases the risk of bleeding. In clinical studies, severe bleeding adverse reactions of epistaxis, gingival bleeding, upper gastrointestinal hemorrhage, and metrorrhagia were each reported in 1% of subjects. Overall, bleeding events occurred in approximately 58% of patients on CABLIVI versus 43% of patients on placebo.

- In the postmarketing setting cases of life-threatening and fatal bleeding were reported in patients receiving CABLIVI.
- The risk of bleeding is increased in patients with underlying coagulopathies (e.g. hemophilia, other coagulation factor deficiencies). It is also increased with concomitant use of CABLIVI with drugs affecting hemostasis and coagulation.
- Avoid concomitant use of CABLIVI with antiplatelet agents or anticoagulants. If clinically significant bleeding occurs, interrupt use of CABLIVI. Von Willebrand factor concentrate may be administered to rapidly correct hemostasis. If CABLIVI is restarted, monitor closely for signs of bleeding.
- Withhold CABLIVI for 7 days prior to elective surgery, dental procedures or other
 invasive interventions. If emergency surgery is needed, the use of von Willebrand factor
 concentrate may be considered to correct hemostasis. After the risk of surgical
 bleeding has resolved, and CABLIVI is resumed, monitor closely for signs of bleeding.

Please see enclosed Full Prescribing Information.

Financial and educational assistance with CABLIVI Patient Solutions



To enroll your patient in these services, you must complete the enrollment form, available from CabliviHCP.com or your sales representative.



SPECIALTY PHARMACY SERVICES

For patients who obtain their medication through Biologics by McKesson:

- The specialty pharmacy coordinates direct-to-home shipment of CABLIVI for a seamless transition upon discharge
- Nurses are available to provide ongoing support and answer questions about CABLIVI
- Pharmacists are available 24 hours a day, 7 days a week
- CABLIVI Patient Solutions help is available Monday through Friday, 8:00 AM to 8:00 PM ET



FINANCIAL ASSISTANCE

- Support is available to cover the cost of CABLIVI co-pay or co-insurance for qualified, commercially insured patients up to the program maximum*
- CABLIVI will be provided at no cost to eligible underinsured or uninsured patients[†]



SUPPLEMENTAL TRAINING

Clinical educators[‡] are available to provide:

- Supplemental education on how to self-administer CABLIVI
- Support in setting up a plan for administering therapy
- Additional in-home support after hospital discharge
- Answers to questions about CABLIVI

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS:

The most common adverse reactions (>15% of patients) were epistaxis (29%), headache (21%) and gingival bleeding (16%).

CONCOMITANT USE OF ANTICOAGULANTS OR ANTIPLATELET AGENTS:

Concomitant use of CABLIVI with any anticoagulant or antiplatelet agent may increase the risk of bleeding. Avoid concomitant use when possible. Assess and monitor closely for bleeding with concomitant use.

PREGNANCY:

There are no available data on CABLIVI use in pregnant women to inform a drug associated risk of major birth defects and miscarriage.

- Fetal/neonatal adverse reactions: CABLIVI may increase the risk of bleeding in the fetus and neonate. Monitor neonates for bleeding.
- Maternal adverse reactions: All patients receiving CABLIVI, including pregnant women, are at risk for bleeding. Pregnant women receiving CABLIVI should be carefully monitored for evidence of excessive bleeding.



^{*}This offer is not valid for prescriptions paid, in whole or in part, by Medicaid, Medicare, Veterans Affairs, Departments of Defense, TRICARE, or similar federal or state programs.

[†]Approval is not guaranteed. Sanofi reserves the right to modify or discontinue the programs at any time.

^{*}CABLIVI clinical educators are paid to provide educational services. They don't provide medical advice. Patients should always consult their physicians with any health care needs.