University of Colorado Hemophilia & Thrombosis Center Pharmacy: NON-FACTOR TREATMENTS

Hemophilia and Thrombosis Center
UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

	HEMLIBRA
MANUFACTURER	GENENTECH (Roche Group)
U.S. LICENSURE DATE	2017
CLASSIFICATION	Bispecific factor IXa- and factor X-directed antibody
SOURCE MATERIAL	Recombinant, Chinese Hamster Ovary (CHO)
FDA APPROVED INDICATIONS	For use in hemophilia A patients with or without inhibitors for: ☑Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
INACTIVE INGREDIENTS	L-arginine, L-histidine, poloxamer 188 and L-aspartic acid
MEAN HALF-LIFE	26.9+/- 9.1 days
DOSING GUIDELINES	Recommended Dosage : Loading dose of 3 mg/kg subcutaneous injection once weekly for the first 4 weeks followed by a maintenance dose of : • 1.5 mg/kg once every week, or • 3 mg/kg once every 2 weeks, or • 6 mg/kg once every 4 weeks
AVAILABLE STRENGTHS	30 mg/mL in a single-dose vial 60 mg/0.4 mL in a single-dose vial 105 mg/0.7 mL in a single-dose vial 150 mg/mL in a single-dose vial

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DRUG ADMINISTRATION	Subcutaneous injection (limit volume to ≤ 2 mL per injection site)
DRUG INTERACTIONS	No drug-drug interaction studies have been conducted with HEMLIBRA. However, clinical experience suggests that a drug interaction exists with HEMLIBRA and aPCC. Thrombotic events reported in 0.5% of patients (2/391) and 5.4% of patients (2/37) who received at least one dose of a aPCC. Consider the benefits and risks if aPCC must be used in patient receiving HEMLIBRA prophylaxis.
MONITORING	HEMLIBRA affects intrinsic pathway clotting-based laboratory tests, including all assays based on aPTT, Bethesda assays for FVIII inhibitor titers and activated clotting time (ACT) aPTT-based assays including clot-based FVIII activity assays with yield artificially shortened aPTT **Laboratory results <u>unaffected</u> by HEMLIBRA:** • Chromogenic FVIII assays will only provide an assessment of HEMLIBRA activity if the assay includes all human reagents. • Thrombin time • Bethesda assays (bovine chromogenic) • One-stage, prothrombin time based, single-factor assay • Immuno-based assays (i.e. ELISA) **Due to the long half-life of HEMLIBRA, effects on coagulation assays may persist for up to 6 months after the last dose.**
STORAGE REQUIREMENTS	◦Refrigerate 2 to 8°C (36°F to 46°F) to expiration date. May be stored at room temperature < 30°C (86 °F) for 7 days. ▫Do not freeze. ▫Store in the original package and protect from light ◦Do not shake ◦Once removed from vial, dose should be administered immediately and any unused portion of Hemlibra should be discarded immediately.
COMMENTS	Most common adverse reactions (incidence >10%) are injection site reactions, headache, and arthralgia) Inform the patient that HEMLIBRA interferes with some laboratory tests that measure blood clotting and may cause a false reading. HEMLIBRA'S effect on coagulation assays may persist for up to 6 months after the last dose due to its long half-life.

NOTE: Recombinant technology may be the ONLY product of choice for patients of Jehovah's Witnesses faith.

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MEDICATION CHART DISCLAIMER

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Disclaimer: Information regarding factor products has been derived from the manufacturer FDA-approved Prescribing Information sheets and other sources and compiled by the staff at the Hemophilia & Thrombosis Center Pharmacy at the University of Colorado. Although every effort is made to assure accuracy, the information was not reviewed by the manufacturer of any particular drug. Information has been provided only as an easily accessible reference of basic information. This information is provided as is without any guarantees or warranty. Dosing information is not intended to replace a physician's judgment on the appropriate dosing regimen for each individual patient.