Important Safety Information & Indication

Indication

HEMLIBRA® is a prescription medicine used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children, ages newborn and older, with hemophilia A with or without factor VIII inhibitors.

What is the most important information I should know about HEMLIBRA?

HEMLIBRA increases the potential for your blood to clot. Carefully follow your healthcare provider's instructions regarding when to use an on-demand bypassing agent or factor VIII, and the dose and schedule to use for breakthrough bleed treatment. HEMLIBRA may cause the following serious side effects when used with activated prothrombin complex concentrate (aPCC; FEIBA®), including:

- **Thrombotic microangiopathy (TMA).** This is a condition involving blood clots and injury to small blood vessels that may cause harm to your kidneys, brain, and other organs. Get medical help right away if you have any of the following signs or symptoms during or after treatment with HEMLIBRA:
  - Confusion
  - Weakness
  - Swelling of arms and legs
  - Yellowing of skin and eyes
  - Stomach (abdomen) or back pain
  - Nausea or vomiting
  - Feeling sick
  - Decreased urination

If aPCC (FEIBA®) is needed, talk to your healthcare provider in case you feel you need more than 100 U/kg of aPCC (FEIBA®) total.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch.
You may also report side effects to Genentech at (888) 835-2555, 24 hrs/day, 7 days/week.

THROMBOTIC MICROANGIOPATHY CASES IN EMICIZUMAB-KXWH CLINICAL TRIALS, EXPANDED ACCESS, COMPASSIONATE USE, AND AFTER FDA APPROVAL[1,2]

- Review of the thrombotic microangiopathy (TMA) adverse events in the emicizumab-kxwh clinical trial program found these events were reported when on average a cumulative amount of >100 U/kg/24 hours of aPCC (FEIBA®) was administered for 24 hours or more to people receiving emicizumab-kxwh prophylaxis.

- As of October 22, 2018, no TMA cases have occurred in the expanded access program or through compassionate use requests.[1]

- As of October 22, 2018, 3 cases of TMA occurred in the HAVEN 1 study and 1 case occurred after the FDA approval of emicizumab-kxwh. HAVEN 1 was a Phase 3 clinical trial in adults and adolescents ≥12 years of age with hemophilia A with factor VIII inhibitors.[2]

Thrombotic Microangiopathy Cases As of October 22, 2018[1,2]

TMA Cases from Clinical Trials, Expanded Access, and Compassionate Use		
3 Cases	On average a cumulative amount of >100 U/kg/24h of aPCC for 24h or more*	Clinical Trial Where Event Occurred
TMA case 1	Yes	HAVEN 1 (Clinical Trial)
TMA case 2	Yes	HAVEN 1 (Clinical Trial)
TMA case 3	Yes	HAVEN 1 (Clinical Trial)
TMA Cases after FDA Approval		
1 Case	On average a cumulative amount of >100 U/kg/24h of aPCC for 24h or more†	
TMA case 1	Yes	

*See the emicizumab-kxwh Medication Guide including, "What is the most important information I should know about HEMLIBRA?"

- Among the 3 TMA cases from the HAVEN 1 clinical trial, 1 occurred in the US, and 2 occurred outside of the US (Ex-US).[1] The TMA case after FDA approval occurred in the US.

If aPCC (FEIBA®) is needed, talk to your healthcare provider in case you feel you need more than 100 U/kg of aPCC (FEIBA®) total.

Your healthcare provider should be the primary source of information about your medical condition and the safe and effective use of any medicine, including emicizumab-kxwh.

You may contact our Medical Communications department with questions specific to this site: (800) 821-8590, 5:00A – 5:00P PST.

References
1. Data on file, Genentech, Inc. October 2018; 2. Oldenburg J et al. *N Engl J Med.* 2017;377:809-818.

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