SERIOUS THROMBOTIC EVENTS (BLOOD CLOTS)

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:

- **Blood clots (thrombotic events).** Blood clots may form in blood vessels in your arm, leg, lung or head. Get medical help right away if you have any of these signs or symptoms of blood clots during or after treatment with HEMLIBRA:
  - Swelling in arms or legs
  - Pain or redness in your arms or legs
  - Shortness of breath
  - Chest pain or tightness
  - Fast heart rate
  - Cough up blood
  - Feel faint
  - Headache
  - Numbness in your face
  - Eye pain or swelling
  - Trouble seeing

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.

SERIOUS THROMBOTIC EVENTS (BLOOD CLOTS) IN EMICIZUMAB-KXWH CLINICAL TRIALS, EXPANDED ACCESS, COMPASSIONATE USE, AND AFTER FDA APPROVAL[1,2]

- Review of the serious thrombotic (blood clots) 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 serious thrombotic events (blood clots) have occurred in the expanded access program or through compassionate use requests. There are no cases of thrombotic events (blood clots) after FDA approval in people who started treatment with emicizumab-kxwh.[1]
- As of October 22, 2018, 2 cases of serious thrombotic events (blood clots) occurred in HAVEN 1. HAVEN 1 was a Phase 3 study in adults and adolescents ≥12 years of age with hemophilia A with factor VIII inhibitors.[2]

Thrombotic (Blood Clot) Cases As of October 22, 2018[1,2]

Thrombotic (Blood Clot) Cases from Clinical Trials, Expanded Access, and Compassionate Use		
2 Cases	On average a cumulative amount of >100 U/kg/24h of aPCC for 24h or more*	Clinical Trial Where Event Occurred
Thrombotic Case 1	Yes	HAVEN 1 (Clinical Trial)
Thrombotic Case 2	Yes	HAVEN 1 (Clinical Trial)

Thrombotic (Blood Clot) Cases after FDA Approval	
0 Cases	On average a cumulative amount of >100 U/kg/24h of aPCC for 24h or more†
0 cases	Not applicable

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

- Among the 2 serious thrombotic events (blood clots) that occurred in the HAVEN 1 clinical trial, 1 occurred in the US, and 1 outside of the US (Ex-US).[1]

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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