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
- **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.

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FATALITIES IN EMICIZUMAB-KXWH CLINICAL TRIALS, EXPANDED ACCESS, COMPASSIONATE USE, AND AFTER FDA APPROVAL[1–3]

Genentech and Roche initiated pivotal clinical trials for people with hemophilia A with factor VIII inhibitors in 2015, and also made emicizumab-kxwh available through the expanded access program, and requests to Roche for compassionate use. In November 2017, the FDA approved emicizumab-kxwh for the treatment of people with hemophilia A with factor VIII inhibitors, and in October 2018, the FDA expanded the approval of emicizumab-kxwh to include the treatment of people with hemophilia A without factor VIII inhibitors.

Patient safety is of the highest importance to us. Genentech and Roche are saddened by any reports of deaths and take all reports of death and safety events seriously.

- All fatalities are evaluated through Genentech and Roche drug safety and reported to regulatory authorities in strict accordance with guidelines and requirements. Systems and processes are in place to monitor the safety of all our medicines, including emicizumab-kxwh, on an ongoing basis.
- This website includes all reported fatalities in people who received emicizumab-kxwh, whether or not the cause of death is related to emicizumab-kxwh.
- As of the last update, no fatalities were assessed by the investigator or treating physician to be related to emicizumab-kxwh.[1]
- Among the 7 fatalities that have happened, 1 occurred in the US, and 6 occurred outside of the US (Ex-US).[1]

As of October 22, 2018[1,3]

	Number of Fatalities
Clinical Trials	2* (HAVEN 1 and STASEY trials)
Expanded Access	1
Compassionate Use	3
After FDA Approval	1†

*One death occurred in HAVEN 1 and one death occurred in STASEY. HAVEN 1 was a Phase 3 clinical trial that studied emicizumab in adults and adolescents ≥12 years of age with hemophilia A with factor VIII inhibitors. STASEY is an ongoing, Ex-US, Phase 3b clinical trial studying the safety and tolerability of emicizumab in adults and adolescents ≥12 years of age with hemophilia A with factor VIII inhibitors.
† An elderly patient who took emicizumab-kxwh for acquired hemophilia A. The cause of death was assessed by the treating physician to be sudden cardiac death, unrelated to emicizumab-kxwh.

- Six of the patients received treatment with emicizumab-kxwh for hemophilia A with factor VIII inhibitors, and 1 patient received treatment with emicizumab-kxwh for acquired hemophilia A.[1]
- Causes of death were assessed as rectal hemorrhage, sepsis, intracranial hemorrhage, pre-existing pseudotumor associated with severe hemophilia A, cecal perforation, sudden cardiac death, and traumatic head injury.[1]

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. Shima M et al. *N Engl J Med.* 2016;374:2044-2053;
3. Oldenburg J et al. *N Engl J Med.* 2017;377:809-818.

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