

Use of emicizumab ▼ prophylaxis might be associated with certain side effects

Side effects

(also known as 'adverse reactions') are unwanted medical problems (such as a headache) that happen while a person is using a drug and that may be related to the drug

~ **400**

people with haemophilia A have been treated with emicizumab in the HAVEN clinical trial programme

Some people taking emicizumab experience one or multiple side effects, but some have none at all

The most common side effect, **seen in 14–31% of people** who took emicizumab during the HAVEN studies, was **redness, tenderness, warmth or itching where the injection was given**

Other side effects that were seen across the HAVEN studies included:

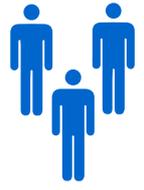
- Swelling of the nasal passages and throat
- Headache
- Joint discomfort

Some side effects can be 'serious'. This means they are life-threatening, need hospital care, or cause lasting problems



The following serious side effects occasionally happened when emicizumab and activated prothrombin complex concentrate (aPCC; FEIBA®) were used together in clinical trials*

Thrombotic microangiopathy (TMA)



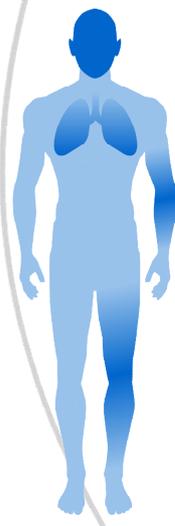
3 cases of TMA have been reported during clinical trials in people taking emicizumab, **all of which were in HAVEN 1**

No more cases of TMA have been reported in clinical trials since following the new dosing guidance for bypassing agents

TMA is a condition involving blood clots and damage to small blood vessels that may cause harm to your kidneys, brain, and other organs

Symptoms may include:

- Stomach (abdomen) or back pain
- Weakness
- Swelling of arms or legs
- Yellowing of skin and eyes
- Confusion
- Nausea or vomiting
- Feeling sick
- Decreased urination



Blood clots (thrombotic events)

4 cases of thrombotic events have been reported during clinical trials in people taking emicizumab, **2 in HAVEN 1, 1 in HAVEN 3 and 1 in STASEY**



These may form in blood vessels in any part of your body

Symptoms may include:

- Swelling in arms or legs
- Pain or redness in arms or legs
- Shortness of breath
- Chest pain or tightness
- Fast heart rate
- Coughing up blood
- Feeling faint
- Headache
- Numbness in face
- Eye pain or swelling
- Trouble seeing

3 participants taking emicizumab died during clinical trials

According to the physician's assessment, the deaths were considered **not to be related to emicizumab treatment**

No new safety concerns were observed in the HAVEN studies with long-term emicizumab prophylaxis

▼Emicizumab is subject to additional monitoring. This will allow quick identification of new safety information. We encourage patients and caregivers to report any adverse reactions to their healthcare professional. *TMA/thrombotic events only occurred with aPCC treatment averaging >100 U/kg daily for ≥24 hours
References: Oldenburg J, et al. N Engl J Med 2017;377:809–18; Mahlangu J, et al. New Engl J Med 2018;379:811–22; Young G, et al. Blood 2019;134:2127–38; Pipe S, et al. Lancet Haematol 2019;6:e295–e305; Callaghan M, et al. ISTH 2019; Jiménez-Yuste V, et al. ISTH 2019; Roche data on file March 2020
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