

What is the observation period after zolbetuximab administration?

Monitor patients during and after infusion with zolbetuximab (at least two hours, or longer if clinically indicated) for hypersensitivity reactions

- Monitor for hypersensitivity reactions with symptoms and signs that are highly suggestive of anaphylaxis (e.g., urticaria, repetitive cough, wheeze and throat tightness/change in voice).¹
- Monitoring is also recommended for patients for signs and symptoms of infusion related reactions including nausea, vomiting, abdominal pain, salivary hypersecretion, pyrexia, chest discomfort, chills, back pain, cough, and hypertension.¹

Additional information

- In the Phase 3 clinical trials SPOTLIGHT and GLOW, patients were observed for two hours following the first zolbetuximab/placebo infusion (Cycle 1 Day1).^{2,3}
 - If Grade ≥ 2 adverse events occurred during the infusion or during the post-infusion observation period, it was recommended to extend subsequent zolbetuximab/placebo infusion times and to continue observing the patient for two hours post zolbetuximab/placebo infusion.^{2,3}
 - If no Grade ≥ 2 adverse events occurred, it was recommended to observe the patient for one hour post-infusion for their subsequent zolbetuximab/placebo infusions.^{2,3}
- In Phase 3 clinical trials SPOTLIGHT and GLOW, mFOLFOX6 and CAPOX could be given during the post-infusion observation period.^{2,3}

References

1. Data on File.
2. Shitara K, Lordick F, Bang YJ, et al. Supplement to: Zolbetuximab plus mFOLFOX6 in patients with CLDN18.2-positive, HER2-negative, untreated, locally advanced unresectable or metastatic gastric or gastro-oesophageal junction adenocarcinoma (SPOTLIGHT): a multicentre, randomised, double-blind, phase 3 trial. *Lancet*. 2023; 401.(10389):1655-1668. Available at: [https://doi.org/10.1016/s0140-6736\(23\)00620-7](https://doi.org/10.1016/s0140-6736(23)00620-7).
3. Shah MA, Shitara K, Ajani JA, et al. Supplement to: Zolbetuximab plus CAPOX in CLDN18.2-positive gastric or gastroesophageal junction adenocarcinoma: the randomized, phase 3 GLOW trial. *Nat. Med.* 2023; 29.(8):2133-2141. Available at: <https://doi.org/10.1038/s41591-023-02465-7>.