Direct Healthcare Professional Communication

November 2026

Identified Risk: Severe Infusion Site Extravasation Events Associated with POLIVY® (Polatuzumab Vedotin)- Update to Warning and Precautions

Dear Healthcare Professional,

Hoffman La Roche Scientific Office in agreement with the General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at the Egyptian Drug Authority would like to inform would like to inform you of the following:

Summary

- Infusion site extravasation (including severe events) is a new identified risk for polatuzumab vedotin. Health care professionals need to be aware of the full range of signs and symptoms of infusion site extravasation and the appropriate medical attention.
- A comprehensive analysis of the data available across the polatuzumab vedotin program has identified cases that provided sufficient evidence of a causal association of infusion site extravasation events with polatuzumab vedotin.

Background

- Polatuzumab vedotin is a CD79b-targeted antibody-drug conjugate that delivers MMAE to B-cells, indicated for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL) in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP), in combination with bendamustine and rituximab (BR) for the treatment of adult patients with DLBCL who have received at least one prior therapy.
- Infusion site extravasation refers to the unintended leakage of a drug or fluids from the vascular system into the paravenous space, which can potentially lead to surrounding skin and soft tissue damage due to toxic effects of the infused drug.

- The signs and symptoms of infusion site extravasation events may range from sensation of burning, tingling, pain, discomfort, swelling and redness at site of injection, which may progress to more severe events like blistering, necrosis, ulceration, and tissue damage such as cellulitis. The onset of these events can occur early, within hours to days, or may be delayed, appearing weeks after the incident of extravasation.
- As of 09 June 2025, an estimated cumulative total of 96,261 patients have received polatuzumab vedotin across post marketing setting and clinical settings. A cumulative analysis of the data available retrieved a total of 31 cases, reporting an event of infusion site extravasation, with a crude reporting rate of 0.03% (31/96,261). Among these 31 cases, four cases of infusion site extravasation events were assessed with sufficient evidence suggesting a probable causal association between infusion site extravasation events and polatuzumab vedotin, with no alternate explanations. These cases included one literature case (index case), one from Non-Interventional Study/NonInterventional Program (NIS/NIP), one from a non-Roche clinical study and one unsolicited post marketing report.
- Based upon the totality of evidence, known class effect of infusion site extravasation event associated with similar-in-class drugs such as enfortumab vedotin and brentuximab vedotin, infusion site extravasation event is considered as associated with polatuzumab vedotin.

Recommendations for Healthcare Professionals

To minimize the risk:

- Ensure adequate venous access prior to initiating the infusion.
- The infusion site should be closely monitored throughout administration for signs of extravasation.
- If extravasation is suspected, the infusion should be stopped immediately.
- The needle should be withdrawn following a brief aspiration. The affected limb should be elevated, and appropriate symptomatic management may be initiated, as required.
- If the symptoms are mild, the remaining dose can be administered in the other limb after ensuring adequate venous access prior to initiating the infusion. Alternatively, if the symptoms are moderate to severe, the infusion may be reinitiated after resolution of events, at the discretion of the treating physician.

The Warnings and Precautions section of the product labels will be updated to reflect this risk. This DHPC (Dear Healthcare Professional Communication) has been disseminated in advance of the label updates to make you aware of the identified risk and to facilitate prompt management of the risk.

References

Singapore (HSA): https://www.hsa.gov.sg/announcements/polivy--polatuzumab-vedotin---new-identified-risk-of-severe-infusion-site-extravasation-events/

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt,

Email: pv.followup@edaegypt.gov.eg

Online reporting: : https://vigiflow-eforms.who-umc.org/eg/med

QR Code:

Hotline: 15301