Based on these observational data, bendamustine appears to have a favorable risk-benefit profile and remains a useful option when considering a management strategy in patients with CLL and NHL.” Martin et al (2017).

Abstract

BACKGROUND: Bendamustine hydrochloride (bendamustine) was approved for first-line treatment of patients with chronic lymphocytic leukemia (CLL) and relapsed indolent B-cell non-Hodgkin’s lymphoma (NHL). Pharmacovigilance data have been collected since bendamustine’s approval to enhance understanding of its long-term safety profile. Here we provide an overview of the pharmacovigilance data for bendamustine that have led to label updates related to safety and administration since its approval.

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RESEARCH DESIGN AND METHODS: Adverse events captured from 12 quarterly postmarketing periodic adverse drug experience reports spanning 2008 to 2015 were included and summarized. AEs were classified as serious or nonserious and expected or unexpected.
RESULTS: Adverse events that resulted in label updates included Stevens-Johnson syndrome, toxic epidermal necrolysis, extravasation, secondary neoplasm, and drug reactions with eosinophilia and systemic symptoms. Preventive measures for tumor lysis syndrome were revised. Although this review may be limited by voluntary reporting, the adverse events reported for bendamustine in a large, heterogeneous population with a long follow-up relative to recently approved treatments provide a much broader understanding of its safety profile.

CONCLUSIONS: Based on these observational data, bendamustine appears to have a favorable risk-benefit profile and remains a useful option when considering a management strategy in patients with CLL and NHL.

Reference:


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