



Bendeka™ (bendamustine) – New Warnings

- On February 9, 2017, the [FDA approved](#) new warnings to the *Warnings and Precautions* section of the [Bendeka \(bendamustine\)](#) drug label regarding hepatotoxicity and drug reaction with eosinophilia and systemic symptoms (DRESS).
- Bendeka is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) and indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with [Rituxan® \(rituximab\)](#) or a rituximab-containing regimen.
 - Efficacy for CLL relative to first line therapies other than [Leukeran® \(chlorambucil\)](#) has not been established.
- Bendamustine is also available as [Treanda®](#). Treanda shares the same indications as Bendeka.
 - Both warnings, hepatotoxicity and DRESS, were added to the Treanda drug label in October 2016.
- Fatal and serious cases of liver injury have been reported with Bendeka.
 - Combination therapy, progressive disease or reactivation of hepatitis B were confounding factors in some patients.
 - Most cases were reported within the first three months of starting therapy.
 - Liver chemistry tests should be monitored prior to and during Bendeka therapy.
- Fatal and serious skin reactions have been reported with Bendeka treatment in clinical trials and post-marketing safety reports.
 - These skin reactions include the toxic skin reactions, Stevens-Johnson Syndrome, toxic epidermal necrolysis, and DRESS, and bullous exanthema and rash.
 - Events occurred when Bendeka was given as a single agent and in combination with other anticancer agents or [allopurinol](#).
 - The skin reactions may be progressive and increase in severity with further treatment.
 - Patients with skin reactions should be monitored closely.
 - If skin reactions are severe or progressive, treatment with Bendeka should be withheld or discontinued.



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