

Treanda[®] (bendamustine) – New Warning

- On October 18, 2016, the FDA approved new updates to the Warnings and Precautions section of the • Treanda (bendamustine) drug label pertaining to hepatotoxicity.
- Treanda is indicated for: .
 - The treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than Leukeran[®] (chlorambucil) has not been established.
 - The treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with Rituxan[®] (rituximab) or a rituximab-containing regimen.
- Fatal and serious cases of liver injury have been reported with Treanda. Most cases were reported within • the first three months of starting therapy.
 - Combination therapy, progressive disease or reactivation of hepatitis B were confounding factors in some patients.
 - Liver chemistry tests should be monitored prior to and during Treanda therapy.



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