

The U.S. Food and Drug Administration (FDA) approved a liquid formulation of Teva Oncology’s TREANDA® (bendamustine HCl) Injection, for intravenous infusion. TREANDA is indicated for treatment of patients with: Chronic Lymphocytic Leukemia (CLL). Efficacy relative to first line therapies other than chlorambucil has not been established. Indolent B-cell non-Hodgkin Lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab containing regimen.

The LIQUID FORMULATION— TREANDA® (bendamustine HCl) Injection is available now.

In addition to the Liquid formulation, TREANDA may still be available for a limited time as a single-use vial of lyophilized powder. All formulations and strengths are outlined below:

Product Name	Strength	NDC [^]	Pack Size	HCPCS Code	WAC Price per Pack	WAC Price per mg
TREANDA liquid formulation	45mg	63459- 0 395-02	1-45mg (0.5mL of solution) amber single-use vial	J9033 – Injection, bendamustine HCL, 1mg	\$1,006.20	\$22.36
TREANDA liquid formulation	180mg	63459- 0 396-02	1-180mg (2mL of solution) amber single-use vial	J9033 – Injection, bendamustine HCL, 1mg	\$4,024.80	\$22.36
TREANDA	25mg	63459- 0 390-08	1-25mg in 8mL amber single-use vial of lyophilized powder	J9033 – Injection, bendamustine HCL, 1mg	\$559.00	\$22.36
TREANDA	100mg	63459- 0 391-20	1-100mg in 20mL amber single-use vial of lyophilized powder	J9033 – Injection, bendamustine HCL, 1mg	\$2,236.00	\$22.36

[^]Note that the product’s NDC code has been “zero-filled” to ensure creation of an 11-digit code that meets CMS standards. The zero-fill location is indicated in bold.

The recommended dosages for TREANDA are identical for both the liquid formulation and the lyophilized powder formulations.

TREANDA has the unique Healthcare Common Procedure Coding System (HCPCS) code of J9033 – Injection, bendamustine HCL, 1mg. J9033 will be used for billing of both TREANDA Liquid Concentrate and TREANDA lyophilized powder formulations.

Important Safety Information

Contraindication: TREANDA is contraindicated in patients with a known hypersensitivity (e.g., anaphylactic and anaphylactoid reactions) to bendamustine.

Myelosuppression: TREANDA caused severe myelosuppression (Grade 3-4) in 98% of patients in the two NHL studies. Three patients (2%) died from myelosuppression-related adverse reactions. If myelosuppression occurs, monitor leukocytes, platelets, hemoglobin (Hgb), and neutrophils frequently. Myelosuppression may require dose delays and/or subsequent dose reductions if recovery to the recommended values has not occurred by the first day of the next scheduled cycle.

Infections: Infection, including pneumonia, sepsis, septic shock, and death have occurred. Patients with myelosuppression following treatment with TREANDA are more susceptible to infections.

Anaphylaxis and Infusion Reactions: Infusion reactions to TREANDA have occurred commonly in clinical trials. Symptoms include fever, chills, pruritus, and rash. In rare instances severe anaphylactic and anaphylactoid reactions have occurred, particularly in the second and subsequent cycles of therapy. Monitor clinically and discontinue drug for severe (Grade 3-4) reactions. Ask patients about symptoms suggestive of infusion reactions after their first cycle of therapy. Consider measures to prevent severe reactions, including antihistamines, antipyretics, and corticosteroids in subsequent cycles in patients who have experienced Grade 1 or 2 infusion reactions.

Tumor Lysis Syndrome: Tumor lysis syndrome associated with TREANDA treatment has occurred. The onset tends to be within the first treatment cycle of TREANDA and, without intervention, may lead to acute renal failure and death. Preventive measures include vigorous hydration and close monitoring of blood chemistry, particularly potassium and uric acid levels. There may be an increased risk of severe skin toxicity when TREANDA and allopurinol are administered concomitantly.

Skin Reactions: Skin reactions have been reported with TREANDA treatment and include rash, toxic skin reactions, and bullous exanthema. In a study of TREANDA (90 mg/m²) in combination with rituximab, one case of toxic epidermal necrolysis (TEN) occurred. TEN has been reported for rituximab. Cases of Stevens-Johnson syndrome (SJS) and TEN, some fatal, have been reported when TREANDA was administered concomitantly with allopurinol and other medications known to cause these syndromes. Where skin

reactions occur, they may be progressive and increase in severity with further treatment. Monitor patients with skin reactions closely. If skin reactions are severe or progressive, withhold or discontinue TREANDA.

Other Malignancies: There are reports of pre-malignant and malignant diseases that have developed in patients who have been treated with TREANDA, including myelodysplastic syndrome, myeloproliferative disorders, acute myeloid leukemia, and bronchial carcinoma. The association with TREANDA therapy has not been determined.

Extravasation Injury: TREANDA extravasations have been reported in post-marketing, resulting in hospitalizations from erythema, marked swelling, and pain. Ensure good venous access prior to starting TREANDA infusion and monitor the intravenous infusion site for redness, swelling, pain, infection, and necrosis during and after administration of TREANDA.

Embryo-fetal Toxicity: TREANDA can cause fetal harm when administered to a pregnant woman. Women should be advised to avoid becoming pregnant while using TREANDA.

Most Common Adverse Reactions: The most common non-hematologic adverse reactions for CLL (frequency $\geq 15\%$) are pyrexia, nausea, and vomiting. The most common non-hematologic adverse reactions for NHL (frequency $\geq 15\%$) are nausea, fatigue, vomiting, diarrhea, pyrexia, constipation, anorexia, cough, headache, weight decreased, dyspnea, rash, and stomatitis. The most common hematologic abnormalities for both indications (frequency $\geq 15\%$) are lymphopenia, anemia, leukopenia, thrombocytopenia, and neutropenia.

Please [click here](#) for the Full TREANDA Liquid Formulation Prescribing Information.

For more information about TREANDA, please visit: <http://www.treanda.com>.