

Truxima® (rituximab-abbs) - New and expanded indications

- On May 23, 2019, the <u>FDA approved</u> Teva and Celltrion's <u>Truxima (rituximab-abbs)</u>, for the treatment of adult patients with previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma (NHL) in combination with (<u>cyclophosphamide</u>, <u>doxorubicin</u>, <u>vincristine</u>, and <u>prednisone</u>) (CHOP) or other anthracycline-based chemotherapy regimens; and with previously untreated and previously treated CD20-positive chronic lymphocytic leukemia (CLL) in combination with <u>fludarabine</u> and cyclophosphamide (FC).
- Previously, Truxima was approved for the following:
 - Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent
 - Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy
 - Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone chemotherapy.
- Truxima is a biosimilar to Genentech and Biogen's <u>Rituxan[®] (rituximab)</u>.
 - Rituxan is also approved for the treatment of adult patients with rheumatoid arthritis, granulomatosis with polyangiitis (Wegener's granulomatosis) and microscopic polyangiitis, and pemphigus vulgaris.
- Similar to Rituxan, Truxima carries a boxed warning for fatal infusion-related reactions, severe
 mucocutaneous reactions, hepatitis B virus reactivation and progressive multifocal
 leukoencephalopathy.
- The most common adverse reactions (≥ 25%) with Truxima use in NHL were infusion-related reactions, fever, lymphopenia, chills, infection and asthenia.
- The most common adverse reactions (≥ 25%) with Truxima use in CLL were infusion-related reactions and neutropenia.
- The recommended dose of Truxima in the expanded NHL indication is 375 mg/m² as an intravenous infusion on day 1 of each cycle of chemotherapy, for up to 8 infusions.
- The recommended dose of Truxima for CLL is 375 mg/m² the day prior to the initiation of FC chemotherapy, then 500 mg/m² on day 1 of cycles 2 to 6 (every 28 days).
- Consult the Truxima drug label for dosing information for all other indications.
- Consult the Rituxan drug label for dosing information for the additional indications.
- Teva and Celltrion's launch plans for Truxima are pending.



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