

Truxima approved as first biosimilar to non-Hodgkin's lymphoma drug

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(HealthDay)—Truxima (rituximab-abbs) has been approved by the U.S. Food and Drug Administration as the first biosimilar to the non-Hodgkin's lymphoma drug Rituxan, the agency said Wednesday.

A biosimilar is a biological product that is approved based on data showing it is "highly similar" to a drug already approved by the FDA, with no "clinically meaningful differences in terms of safety, purity and potency," the agency said in a news release.

Truxima, as with Rituxan, is approved to treat adults with CD20-positive, B-cell non-Hodgkin's lymphoma. The most common side effects of Truxima are infusion reactions, fever, low blood lymphocytes, chills, infection and weakness.

The drug's label includes a boxed warning that [users](#) also may be at increased risk of fatal infusion reactions, severe skin and mouth reactions, reactivation of hepatitis B, and a rare deadly brain infection known as PML.

Users should not receive [vaccinations](#) while in treatment with Truxima, the agency warned, adding that women who are pregnant or breastfeeding shouldn't take the [drug](#).

Truxima is produced by the South Korean drugmaker Celltrion. Rituxan, produced by the San Francisco firm Genentech, was approved in 1997.

More information: Visit the [FDA](#) to learn more.

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