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Generic Name:

Rituximab-abbs

Trade Name:

Truxima

Company:

Celltrion

Notes:

FDA approved [rituximab-abbs](#) as the first biosimilar to rituximab (Rituxan) for the treatment of adult patients with CD20-positive, B-cell non-Hodgkin's lymphoma (NHL) to be used as a single agent or in combination with chemotherapy. Rituximab-abbs is the first biosimilar to be approved in the United States for the treatment of NHL. It has been approved as a biosimilar, not as an interchangeable product.

Approval was based on a review of evidence that included extensive structural and functional characterization, animal study data, human pharmacokinetic data, clinical immunogenicity data, and other clinical data that demonstrate the drug is biosimilar to Rituxan.

The most common adverse effects are infusion reactions, fever, abnormally low level of lymphocytes in the blood, chills, infection, and weakness. Health care providers are advised to monitor patients for tumor lysis syndrome, cardiac adverse reactions, damage to kidneys, and bowel obstruction and perforation.

Patients should not receive vaccinations while in treatment. Women who are pregnant or breastfeeding should not take the drug because it may cause harm to a developing fetus or newborn baby.

The labeling contains a boxed warning to alert health professionals and patients about increased risks of the following: fatal infusion reactions, severe skin and mouth reactions, some with fatal outcomes; Hepatitis B virus reactivation, which may cause serious liver problems including liver failure and death; and progressive multifocal leukoencephalopathy, a rare, serious brain infection that can result in severe disability or death.

The new biosimilar must be dispensed with a patient Medication Guide that provides important information about the drug's uses and risks.

Medication Monitor Categories:

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