Generic Name:
Rituximab
Trade Name:
Rituxan
Company:
Genentech
Notes:

Genentech announced an update to the rituximab label to include information on follow-up treatment of adult patients with granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) who have achieved disease control with induction treatment.

GPA and MPA are two types of antineutrophil cytoplasmic antibody?associated vasculitis, or inflammation of the blood vessels, that largely affects the small blood vessels of the kidneys, lungs, and a variety of other organs.

The label update was based on data from a Roche-supported study by the French Vasculitis Study Group showing that treatment with the rituximab regimen (rituximab and glucocorticoids) resulted in fewer major relapses by month 28 compared with treatment with azathioprine. The observed safety profile was consistent with that previously observed in this patient population.

In combination with glucocorticoids, rituximab was approved by FDA in 2011 for adult patients with GPA and MPA with the precaution that limited data were available on the safety and efficacy of subsequent courses of rituximab in patients with GPA and MPA, and that the safety and efficacy of retreatment with rituximab had not been established. As part of this label update, the precaution has been removed from the rituximab prescribing information.

Medication Monitor Categories:
Supplemental Approvals