
Specific Changes: Consider updating the NCCN Guidelines with results from the recently presented Phase III RATE Trial, which evaluated the safety of accelerated infusions of Rituxan in patients with previously untreated diffuse large B-cell lymphoma (DLBCL) and follicular NHL.1,2

FDA Clearance: Rituxan is FDA-approved for the treatment of patients with low-grade or follicular NHL, DLBCL, and chronic lymphocytic leukemia (CLL).3 Please refer to the enclosed prescribing information for the full FDA-approved indications, safety information and recommended dosing/administration.

Rationale: In the RATE trial patients with previously untreated DLBCL and follicular NHL, and no history of significant cardiovascular disease were treated with 6-8 cycles of Rituxan plus cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP) or Rituxan plus cyclophosphamide, vincristine and prednisone (R-CVP), respectively.1,2 Patients (n=363) who tolerated the first dose of rituximab (Cycle 1) at the standard infusion rate were administered subsequent doses of rituximab over a total of 90 minutes.

The incidence of Grade 3 infusion-related reactions (IRRs) for the first 90-minute Rituxan infusion (Cycle 2) was 1.1%; no Grade 4 IRRs were reported.1,2 IRRs included rash, bronchospasm, hypersensitivity, and abdominal pain. For Cycles 2-8, the incidence of Grade 3/4 IRRs was 2.8% and included (additionally) abdominal pain/diarrhea, nausea, angina, asthenia, peripheral edema/ascites and hypertension. In the RATE trial, no acute fatal IRRs were observed. Per the prescribing information, Rituxan has been associated with serious, sometimes fatal, adverse IRRs.

The following enclosures are included for your review (copyright-paid where applicable):

- Dakhil S, Hermann R, Chai A, et al. Final results of a single arm Phase III multicenter, open-label study of rituximab administered by faster infusion in patients with previously untreated diffuse large B-cell (DLBCL) or follicular non-Hodgkin’s lymphoma (FL). Presented at the 53rd ASH Annual Meeting and Exposition in San Diego, CA; December 10-13, 2011. ASH Poster #2703
- Dakhil S, Hermann R, Chai A, et al. Final results of a single arm Phase III multicenter, open-label study of rituximab administered by faster infusion in patients with previously untreated diffuse large B-cell (DLBCL) or follicular non-Hodgkin’s lymphoma (FL). Blood 2011;118.ASH Abstract #2703
- Rituxan Prescribing Information
Cited References

1. Dakhil S, Hermann R, Chai A, et al. Final results of a single arm Phase III multicenter, open-label study of rituximab administered by faster infusion in patients with previously untreated diffuse large B-cell (DLBCL) or follicular non-Hodgkin's lymphoma (FL). Presented at the 53rd ASH Annual Meeting and Exposition in San Diego, CA; December 10-13, 2011. ASH Poster #2703
2. Dakhil S, Hermann R, Chai A, et al. Final results of a single arm Phase III multicenter, open-label study of rituximab administered by faster infusion in patients with previously untreated diffuse large B-cell (DLBCL) or follicular non-Hodgkin's lymphoma (FL). Blood 2011;118. ASH Abstract #2703
3. Rituxan Prescribing Information