RILAST
(Rituximab)

Rituximab is a genetically engineered chimeric murine/human monoclonal antibody directed against the CD20 antigen found on the surface of normal and malignant B lymphocytes. The antibody is an IgG1 kappa immunoglobulin containing murine light and heavy-chain variable region sequences and human constant region sequences. Rituximab is composed of two heavy chains of 451 amino acids and two light chains of 213 amino acids.

Dosage Form

Solution for Infusion.

Clinical Pharmacology – Mechanism of Action

Rituximab is a monoclonal antibody that targets the CD20 antigen, which is expressed on the surface of pre-B and mature B-lymphocytes. Upon binding to CD20, Rituximab mediates B-cell lysis. Possible mechanisms of cell lysis include complement-dependent cytotoxicity (CDC) and antibody-dependent cell-mediated cytotoxicity (ADCC).

Indication

Rituximab is indicated in adults for the following indications:

- Non-Hodgkin's lymphoma (NHL)

o Rituximab is indicated for the treatment of previously untreated adult patients with stage III-IV follicular lymphoma in combination with chemotherapy.

o Rituximab maintenance therapy is indicated for the treatment of adult follicular lymphoma patients responding to induction therapy.

o Rituximab monotherapy is indicated for the treatment of adult patients with stage III-IV follicular lymphoma who are chemo-resistant or are in their second or subsequent relapse after chemotherapy.

o Rituximab is indicated for the treatment of adult patients with CD20 positive diffuse large B cell non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) chemotherapy.

o Rituximab in combination with chemotherapy is indicated for the treatment of pediatric patients (aged ≥ 6 months to < 18 years old) with previously untreated advanced stage CD20 positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL)/Burkitt leukemia (mature B-cell acute leukemia) (BAL) or Burkitt-like lymphoma (BLL).

- Chronic lymphocytic leukemia (CLL)

Rituximab in combination with chemotherapy is indicated for the treatment of patients with previously untreated and relapsed/refractory CLL. Only limited data are available on efficacy and safety for patients previously treated with monoclonal antibodies, including Rituximab, or patients refractory to previous Rituximab plus chemotherapy.

- Rheumatoid arthritis

Rituximab in combination with methotrexate is indicated for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to other disease-modifying anti-rheumatic drugs (DMARD) including one or more tumor necrosis factor (TNF) inhibitor therapies. Rituximab has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate.

- Granulomatosis with polyangiitis and microscopic polyangiitis

Rituximab, in combination with glucocorticoids, is indicated for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA).

- Pemphigus vulgaris

Rituximab is indicated for the treatment of adult patients with moderate to severe pemphigus vulgaris (PV).

Dosage and Administration

Administer only as an intravenous infusion, do not administer as an IV push or bolus. Rituximab should be administered only by a healthcare professional with appropriate medical support to manage severe infusion reactions that can be fatal if they occur. The dose of NHL is 375mg/m2. The dose of CLL is 375mg/m2 in the first cycle and 500mg/m2 in cycles 2-6, in combination with FC (Fludarabine & Cyclophosphamide), administered every 28 days.

Storage and Handling

Rilast must be stored at 2 – 8°C.

Packaging Information

The primary container is a clear glass vial, pre-sterilized, neutral with a 20 mm chlorobutyl rubber stopper used to fill Rituximab DP.

Manufactured By

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