

TORITZ T

For the use of Oncologist and Rheumatologist only

Abbreviated Prescribing information for TORITZ T [Rituximab Injection 100mg/10ml and 500mg/50ml] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Rituximab is monoclonal antibody with antineoplastic activity which binds to the transmembrane antigen, CD20, a non-glycosylated phosphoprotein, located on pre -B and mature B lymphocytes.

INDICATION: Indicated for the treatment of patients with Non-Hodgkin's Lymphoma (NHL) and Rheumatoid Arthritis (RA) who have an inadequate response or intolerance to one or more Tumor Necrosis Factor (TNF) inhibitor therapies.

DOSAGE AND ADMINISTRATION: Administer only as an intravenous infusion. Do not administer as an intravenous push or bolus. Administer under the close supervision of an experienced healthcare professional, and in an environment where full resuscitation facilities are immediately available. The dose for NHL is 375 mg/m². The dose for RA is two-1000 mg intravenous infusions separated by 2 weeks (one course) every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks. Methylprednisolone 100 mg intravenous or equivalent glucocorticoid is recommended 30 minutes prior to each infusion.

CONTRAINDICATION: Hypersensitivity to the active substance or to murine proteins, or to any of the other excipients, active severe infections, severely immunocompromised state and severe heart failure or severe, uncontrolled cardiac disease.

WARNINGS & PRECAUTIONS: Risk of progressive multifocal leukoencephalopathy (PML), infusion related reactions (IRRs) (syndrome of cytokine release, tumour lysis syndrome, anaphylactic and hypersensitivity reactions), cardiac disorders, haematological toxicities, serious infections including fatalities, severe skin reactions such as Toxic Epidermal Necrolysis (Lyell's syndrome) and Stevens-Johnson syndrome, hepatitis B reactivation and late neutropenia. Not recommended: vaccination with live virus vaccine and to use in MTX-naïve patients.

ADVERSE REACTIONS: Infusion reactions, fever, lymphopenia, chills, infection, asthenia, upper respiratory tract infection, bronchitis, serious infections, cardiovascular events, Hepatitis B reactivation with fulminant hepatitis, renal toxicity, bowel obstruction and perforation.

MARKETED BY:



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IN/ TORITZ T 100,500mg/Mar-16/01/AbPI
(Additional information is available on request)