TORITZ MS

For the use of Oncologist and Rheumatologist only

Abbreviated Prescribing information for TORITZ MS [Rituximab Injection I.P.]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:
MECHANISM OF ACTION: Rituximab targets B lymphocyte by attaching to CD 20 proteins on the cell surface.

INDICATIONS: Non-Hodgkin's Lymphoma (NHL) TORITZ MS (rituximab) is indicated for the treatment of: • Previously untreated patients with stage III- IV follicular lymphoma in combination with chemotherapy• Follicular lymphoma responding to induction therapy• Stage III-IV follicular lymphoma who are chemo resistant or are in their second or subsequent relapse after chemotherapy• Patients with CD20-positive diffuse large B-cell non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) chemotherapy. **Rheumatoid Arthritis (RA)** • The treatment of adult patients with active rheumatoid arthritis who have an inadequate response or intolerance to one or more tumor necrosis factor (TNF) inhibitor therapies. **Chronic Lymphocytic Leukemia (CLL)** Rituximab is indicated, in combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive CLL. **Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)** Rituximab, in combination with glucocorticoids, is indicated for the treatment of adult patients with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA). **Pemphigus Vulgaris (PV)** Rituximab is indicated for the treatment of adult patients with moderate to severe pemphigus vulgaris.

DOSAGE AND ADMINISTRATION: Administer only as an Intravenous Infusion. Do not administer as an intravenous push or bolus. First Infusion: Initiate infusion at a rate of 50 mg/hr. In the absence of infusion toxicity, increase infusion rate by 50 mg/hr increments every 30 minutes, to a maximum of 400 mg/hr. Subsequent Infusions: *Standard infusion*: Initiate infusion at a rate of 100 mg/hr. In the absence of infusion toxicity, increase rate by 100 mg/hr increments at 30-minute intervals, to a maximum of 400 mg/hr**.**

CONTRAINDICATION: *Contraindications for use in non-Hodgkin's lymphoma*• Hypersensitivity to the active substance or to murine proteins, or to any of the other excipients • Active, severe infections • Patients in a severely immunocompromised state*. Contraindications for use in rheumatoid arthritis* • Hypersensitivity to the active substance or to murine proteins, or to any of the other excipients • Active, severe infections • Patients in a severely immunocompromised state • Severe heart failure (New York Heart Association Class IV) or severe, uncontrolled cardiac disease.

WARNINGS & PRECAUTIONS: Fatal infusion reactions, severe mucocutaneous reactions, hepatitis b virus reactivation and progressive multifocal leukoencephalopathy. Infusion reaction, Severe Mucocutaneous reaction, Hepatitis B Virus Reactivation, Progressive Multifocal Leukoencephalopathy (PML), Tumor Lysis Syndrome (TLS), Infections, Cardiovascular, Renal, Bowel obstruction and perforation, immunization, laboratory monitoring, embryo-fetal toxicity, Concomitant Use with Biologic Agents and Disease-modifying antirheumatic drugs (DMARDs) other than Methotrexate in RA, Observe patients closely for signs of infection if biologic agents and/or DMARDs are used concomitantly.

DRUG INTERACTIONS: There have been no formal drug interaction studies performed with TORITZ MS. However, the existing data suggest that rituximab does not affect the pharmacokinetics of drugs which are used in combination with rituximab.

ADVERSE REACTIONS: NHL (≥25%): infusion reactions, fever, lymphopenia, chills, infection, and astheniaRA (≥ 10%): upper respiratory tract infection, nasopharyngitis, urinary tract infection, and

bronchitis (other important adverse reactions include infusion reactions, serious infections, and cardiovascular events) Serious adverse reactions: Infusion reactions mucocutaneous reactions, Hepatitis B reactivation with fulminant hepatitis, progressive multifocal leukoencephalopathy, tumor lysis syndrome, Infections, cardiac arrhythmias, renal toxicity, bowel obstruction and perforation.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/TORITZ MS 500 mg/50 mL/MAY-2026/04/ABPI

(Additional information is available on request)