

LYMPHTOR 100

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for LYMPHTOR 100 [Bendamustine Injection I.P. 100 mg]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Lurasidone Bendamustine hydrochloride is a bifunctional mechlorethamine derivative containing a purine-like benzimidazole ring. Mechlorethamine and its derivatives form electrophilic alkyl groups. These groups form covalent bonds with electron-rich nucleophilic moieties, resulting in interstrand DNA cross links. The bifunctional covalent linkage can lead to cell death via several pathways. Bendamustine hydrochloride is active against both quiescent and dividing cells. The exact mechanism of action of Bendamustine hydrochloride remains unknown.

INDICATIONS: Lymphtor is indicated For the treatment of patients with chronic lymphocytic leukemia and For the use in Indolent B-cell Non Hodgkin's Lymphoma (NHL).

DOSAGE AND ADMINISTRATION: Monotherapy for *chronic lymphocytic leukaemia* 100 mg/m² body surface area bendamustine hydrochloride on days 1 and 2; every 4 weeks. Monotherapy for indolent *non-Hodgkin's lymphomas* refractory to rituximab. 120 mg/m² body surface area bendamustine hydrochloride on days 1 and 2; every 3 weeks. *Multiple myeloma* 120 - 150 mg/m² body surface area bendamustine hydrochloride on days 1 and 2, 60 mg/m² body surface area prednisone I.V. or per OS on days 1 to 4; every 4 weeks.

CONTRAINDICATION: Hypersensitivity Bendamustine hydrochloride is contraindicated in patients with a known hypersensitivity,(e.g., anaphylactic and anaphylactoid reactions) to bendamustine or mannitol, During breastfeeding, Severe hepatic impairment (serum bilirubin > 3.0 mg/dl), Jaundice, Severe bone marrow suppression and severe blood count alterations (leukocyte and/or platelet values dropped to < 3,000/ μ l or < 75,000/ μ l, respectively), Major surgery less than 30 days before start of treatment, infections, especially involving leukocytopenia, Yellow fever vaccination.

WARNINGS & PRECAUTIONS: Warning: Cytotoxic Drug: To be supplied against demand from Cancer Hospitals, Institutions and against prescription of cancer specialist only. *Myelosuppression:* Patients treated with Bendamustine hydrochloride are likely to experience myelosuppression. *Infections:* Infection, including pneumonia and sepsis, has been reported in patients in clinical trials and in post marketing reports. *Hepatitis B reactivation:* Reactivation of hepatitis B in patients who are chronic carriers of this virus has occurred after these patients received bendamustine hydrochloride. *Tumor Lysis Syndrome:* Tumor lysis syndrome associated with Bendamustine hydrochloride treatment has been reported in patients in clinical trials and in post-marketing reports. *Skin Reactions:* A number of skin reactions have been reported in clinical trials and post-marketing safety reports. *Cardiac disorders:* During treatment with bendamustine hydrochloride the concentration of potassium in the blood of patients with cardiac disorders must be closely monitored and potassium supplement must be given. when K <3.5 mEq/l and ECG measurement must be performed. *Nausea, vomiting:* An antiemetic may be given for the symptomatic treatment of nausea and vomiting. *Anaphylaxis:* Infusion reactions to bendamustine hydrochloride have occurred commonly in reported clinical trials. Symptoms are generally mild and include fever, chills, pruritus and rash. In rare instances severe anaphylactic and anaphylactoid reactions have occurred. *Contraception:* Bendamustine hydrochloride is teratogenic and mutagenic. *Extravasation* An extravasal injection should be stopped immediately.

DRUG INTERACTIONS: Myelosuppressive agents, co-administered medicinal products on the bone marrow may be potentiated. Combination of bendamustine with cyclosporine or tacrolimus Cytostatics can reduce antibody formation following live-virus vaccination and increase the risk of infection, CYP1A2 inhibitors such as fluvoxamine, ciprofloxacin, acyclovir and cimetidine exists.

ADVERSE REACTIONS: *Very common side effects (may affect more than 1 in 10 people):* low counts of white blood cells (disease-fighting cells in your blood), decrease in the red pigment of the blood, (haemoglobin: a protein in red blood cells that carries oxygen throughout the body), low counts of platelets (colourless blood cells that help blood clot), infections, feeling sick (nausea), vomiting, mucosal inflammation, headache, increased blood level of creatinine (a chemical waste product that is produced by your muscle), increased blood level of urea (a chemical waste product), fever, fatigue, *Common side effects (may affect up to 1 in 10 people):* bleeding

(haemorrhage),disturbed metabolism caused by dying cancer, cells releasing their contents into the blood stream, reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia),low counts of neutrophils (a common type of white blood cell important to fighting off infections),hypersensitivity reactions such as allergic inflammation of the skin (dermatitis), nettle rash (urticaria),a rise in liver enzymes AST/ALT (which may, indicate inflammation or damage to cells in the liver),a rise in the enzyme alkaline phosphatase (an enzyme made mostly in the liver and bones),a rise in bile pigment (a substance made during the normal breakdown of red blood cells),low potassium blood levels (a nutrient that is necessary for the function of nerve and muscle cells, including those in your heart),disturbed function (dysfunction) of the heart (palpitations, angina pectoris),disturbed heart rhythms (arrhythmia),low or high blood pressure (hypotension or hypertension),disturbed lung function, diarrhoea, constipation, sore mouth (stomatitis),loss of appetite, hair loss, skin changes, missed periods (amenorrhoea),pain, insomnia, chills, dehydration, dizziness, itchy rash (urticaria),*Uncommon side effects (may affect up to 1 in 100 people)*:accumulation of fluid in the heart sac (escape of fluid into the pericardial space),ineffective production of all blood cells (myelodysplastic syndrome),acute leukemia, heart attack, chest pain (myocardial infarct) heart failure, *Rare side effects (may affect up to 1 in 1,000 people)*:infection of the blood (sepsis),severe allergic hypersensitivity reactions (anaphylactic reactions),reduction in your bone marrow function, which may make you feel unwell or show up in your, blood tests, signs similar to anaphylactic reactions (anaphylactoid reactions), drowsiness, loss of voice (aphonia),acute circulatory collapse (failure of blood circulation mainly from a cardiac origin with failure to maintain the supply of oxygen and other nutrients to the tissues and removing toxins),reddening of the skin (erythema),inflammation of the skin (dermatitis),itching (pruritus),skin rash (macular exanthema). excessive sweating (hyperhidrosis),*Very rare side effects (may affect up to 1 in 10,000 people)*:Primary atypical inflammation of the lungs (pneumonia).Break-down of red blood cells. Rapid decrease in blood pressure sometimes with skin reactions or rash (anaphylactic shock).Disturbed sense of taste. Altered sensations (paraesthesia) and malaise and pain in the limbs (peripheral neuropathy), Serious condition resulting in the blockade of specific receptor in the nervous systems, Disorders of the nervous system, Lack of coordination (ataxia),Inflammation of the brain (encephalitis),Increased heart rate (tachycardia),Inflammation of the veins (phlebitis),Formation of tissue in the lungs (fibrosis of the lungs),Bleeding inflammation of the gullet (haemorrhagic oesophagitis),Bleeding of stomach or gut, Infertility and Multiple organ failure.

MARKETED BY:

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Torrent Pharmaceuticals Limited.

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(Additional information is available on request)