NOJETOR

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

Abbreviated Prescribing information for **NOJETOR** [Lenalidomide Capsules 10 mg and 25 mg] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: antineoplastic properties. Lenalidomide inhibits proliferation and induces apoptosis of certain hematopoietic tumor cells including multiple myeloma, mantle cell lymphoma, and del (5q) myelodysplastic syndromes in vitro.

INDICATION: For the treatment of patients with transfusion dependent anemia due to low or intermediate -1- risk myelodysplastic syndrome (MDS) associated with deletion 5q cytogenic abnormality with or without additional cytogenic abnormalities.

DOSAGE AND ADMINISTRATION: **Myelodysplastic Syndromes:-** The recommended starting dose of lenalidomide is 10 mg daily. Treatment is continued or modified based upon clinical and laboratory findings.

CONTRAINDICATION: Pregnancy Lenalidomide can cause fetal harm when administered to a pregnant female. **Allergic Reactions** Lenalidomide is contraindicated in patients who have demonstrated hypersensitivity (e.g., angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis) to lenalidomide.

WARNINGS & PRECAUTIONS: Lenalidomide can cause significant neutropenia and thrombocytopenia, Venous thromboembolic events (deep venous thrombosis and pulmonary embolism) and arterial thromboses are increased in patients treated with lenalidomide, Hepatic failure, including fatal cases, has occurred in patients treated with lenalidomide in combination with dexamethasone, Fatal instances of tumor lysis syndrome, tumor flare reaction and impaired stem cell mobilization have been reported during treatment with lenalidomide,

DRUG INTERACTIONS: Digoxin, warfarin and Erythropoietic agents, or other agents that may increase the risk of thrombosis, such as estrogen containing therapies, should be used with caution in multiple myeloma patients receiving lenalidomide with dexamethasone.

ADVERSE REACTIONS: Embryo-Fetal Toxicity, Neutropenia and thrombocytopenia, Venous and arterial thromboembolism, Increased Mortality in Patients with CLL, Second Primary Malignancies, Hepatotoxicity, Allergic Reaction, Tumor lysis syndrome, Tumor flare reactions, Neutropenia, Anemia, Thrombocytopenia, Leukopenia, Lymphopenia, Fatigue, Pyrexia, Peripheral edema, Chest Pain, Lethargy, Constipation, Diarrhea, Nausea, Vomiting, Abdominal Pain, Dry Mouth, Muscle cramp, pancytopenia, autoimmune hemolytic anemia, bradycardia, myocardial infarction, angina pectoris, hirsutism, blindness, ocular hypertension, gastrointestinal hemorrhage, glossodynia, malaise, liver function tests abnormal, alanine aminotransferase increased, cerebral ischemia, mood swings, hallucination, loss of libido, erectile dysfunction, cough, hoarseness, exanthema and skin hyperpigmentation.

MARKETED BY:

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IN/ NOJETOR 10,25mg/Nov-2015/01/ABPI

(Additional information is available on request)