PEMOTIDE

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.
Abbreviated Prescribing information for PEMOTIDE (Pemetrexed Injection I.P.**)**

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: PEMOTIDE (pemetrexed) is a multi-targeted anti-cancer antifolate agent that exerts its action by disrupting crucial folate-dependent metabolic processes essential for cell replication.

DOSAGE AND ADMINISTRATION: PEMOTIDE should be administered as an intravenous infusion over 10 minutes on the first day of each 21-day cycle.

CONTRAINDICATION: Pemetrexed for injection is contraindicated in patients who have a history of severe hypersensitivity reaction to pemetrexed or to any other ingredient used in the formulation; contraindicated during breast-feeding; contraindicated with concomitant yellow fever vaccine.

WARNINGS & PRECAUTIONS:

- Patients should be monitored for myelosuppression during therapy and pemetrexed should not be given to patients until absolute neutrophil count (ANC) returns to ≥ 1500 cells/mm and platelet count returns to ≥ 100,000 cells/mm.
- All patients treated with pemetrexed must be instructed to take folic acid and vitamin B as a prophylactic measure to reduce treatment-related toxicity.
- Skin reactions have been reported in patients not pre-treated with a corticosteroid. Pre-treatment with dexamethasone (or equivalent) can reduce the incidence and severity of skin reactions.
- The use of pemetrexed in patients with creatinine clearance of < 45 ml/min is not recommended.
- Patients should be regularly monitored for acute tubular necrosis, decreased renal function and signs and symptoms of nephrogenic diabetes insipidus (e.g. hypernatraemia).
- Drainage of third space fluid collection prior to pemetrexed treatment should be considered, but may not be necessary.
- Patients should receive adequate antiemetic treatment and appropriate hydration prior to and/or after receiving treatment.
- Serious cardiovascular events, including myocardial infarction and cerebrovascular events have been uncommonly reported during clinical studies with pemetrexed, usually when given in combination with another cytotoxic agent.
- Immunodepressed status is common in cancer patients. As a result, concomitant use of live attenuated vaccines is not recommended.
- Owing to the possibility of pemetrexed treatment causing irreversible infertility, men are advised to seek counselling on sperm storage before starting treatment.
- Women of childbearing potential must use effective contraception during treatment with pemetrexed.

- Cases of radiation pneumonitis have been reported in patients treated with radiation either prior, during or subsequent to their pemetrexed therapy. Particular attention should be paid to these patients and caution exercised with use of other radiosensitising agents.

ADVERSE REACTIONS: Neutrophils/Granulocytes decreased, Leukocytes decreased, Hemoglobin decreased, Platelets decreased, Dehydration, Neuropathy- Sensory, Taste disturbance, Conjunctivits, Diarrhoea, Vomiting, Stomatitis/ Pharyngitis, Nausea, Anorexia, Constipation, Dyspepsia, Rash, Alopecia, Creatinine elevation, Creatinine clearance decreased, Fatigue

MARKETED BY

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TORRENT PHARMACEUTICALS LTD.

IN/ PEMOTIDE 100, 500 mg/OCT-20/03/ABPI

(Additional information is available on request)