

NORMABRAIN

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

Abbreviated Prescribing information for NORMABRAIN INJECTION (Piracetam 200 mg/ml)

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

PHARMACOLOGICAL PROPERTIES: Its mode of action in cortical myoclonus is as yet unknown. Exerts its haemorrhheological effects on the platelets, red blood cells, and vessel walls by increasing erythrocyte deformability and by decreasing platelet aggregation, erythrocyte adhesion to vessel walls and capillary vasospasm.

INDICATION: Indicated for patients suffering from myoclonus of cortical origin, irrespective of aetiology, and should be used in combination with other anti-myoclonic therapies.

DOSAGE AND ADMINISTRATION: Adults: Initial dose of 7.2 gm/day, followed by increased in 4.8gm /day every 3 to 4 days up to a maximum of 24g/day, given in either 2 or 3 divided doses daily. In patients with an acute episode attempt should be made every 6 months to decrease or discontinue the medicinal treatment. Dose should be reduced by 1.2 g every two days. **Elderly:** Dose adjustment is recommended in patients with compromised renal Function. If needed regular evaluation of the creatinine clearance is required to allow dosage adaptation. If renal creatinine clearance is (1) >80ml/min: usual daily dose, 2 to 4 sub-doses, (2) 50-79ml/min: 2/3 usual daily dose, 2 or 3 subdoses, (3) 30-49ml/min: 1/3 usual daily dose, 2 sub-doses, (4) < 30ml/min: 1/6 usual daily dose, 1 single intake. Contraindicated in end stage renal disease. No dose adjustment is needed in patients with solely hepatic impairment. May be taken with or without food and to be swallowed with liquid.

CONTRAINDICATION: Patients with severe renal impairment (renal creatinine clearance of less than 20 ml per minute), hepatic impairment and to those under 16 years of age, patients with cerebral haemorrhage, suffering from Huntington's Chorea, hypersensitivity to piracetam and other pyrrolidone derivatives or any of the excipients.

WARNINGS & PRECAUTIONS: Caution is recommended in patients with severe haemorrhage, at risk of bleeding such as gastrointestinal ulcer, haemostasis, history of haemorrhagic CVA, undergoing major surgery including dental surgery, using anticoagulants or platelet antiaggregant drugs including low dose aspirin, in cases of renal insufficiency, creatinine clearance evaluation in elder patient with prolonged treatment and avoid abrupt discontinuation of treatment.

DRUG INTERACTIONS: Interacts with thyroid hormones

ADVERSE REACTIONS: Haemorrhagic disorder, anaphylactoid reaction, nervousness, depression, hyperkinesia, aggravated epilepsy, somnolence, asthenia and weight gain.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

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(Additional information is available on request)