## EDGE<sup>TM</sup>-P PLUS

**For the use only of a Registered Medical Practitioner or Hospital or a Laboratory** Abbreviated Prescribing information for EDGE<sup>TM</sup>-P PLUS (Evening Primrose Oil and Mecobalamin capsule) [Please refer the complete prescribing information available at <u>www.torrentpharma.com</u>]

**PHARMACOLOGICAL PROPERTIES**: Evening primrose oil: Prostaglandin precursors; Mecobalamin: Co-enzyme in nucleic acid synthesis.

INDICATION: Fibrocystic Breast Disease; Mastalgia.

**DOSAGE AND ADMINISTRATION**: 1-2 Soft Gelatin CAPS per day for 3-6 months. Dose may be increased, if necessary according to physician's discretion.

**CONTRAINDICATION**: Hypersensitivity to any of the ingredients.

**WARNINGS & PRECAUTIONS:** *Evening primrose oil:* Caution required for patients with/history of epilepsy/schizophrenia; increase risk of bruising/bleeding; Surgery. *Mecobalamin:* Caution required for suspected vitamin B12 deficiency (Blood parameters monitoring needed); Patients with Leber's disease or tobacco amblyopia.

**DRUG INTERACTIONS**: *Mecobalamin*: Interacting with neomycin, aminosalicylic acid, histamine H2-antagonists, omeprazole, colchicine, oral contraceptives, and parenteral chloramphenicol. *Evening primrose oil*: Phenytoin and other anticonvulsants; Anti-coagulant Antiplatelet drugs; NSAIDs, and Phenothiazines.

**ADVERSE REACTIONS**: *Mecobalamin*: Hypersensitivity reactions (allergic reaction, generalized morbilliform exanthems, urticaria, or generalised pruritus, bronchospasm, oropharyngeal angioedema, anorexia, nausea, vomiting, diarrhoea). *Evening primrose oil*: nausea, headache, softening of the stools, bruising, Seizures.

MARKETED BY: TORRENT PHARMACEUTICALS LTD. Torrent House, Off Ashram Road, Ahmedabad-380 009, INDIA IN/ EDGE P PLUS /MAR 2015/01/AbPI (Additional information is available on request)