

PREGEB FORTE

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only
Abbreviated Prescribing information for PREGEB FORTE (Pregabalin, Mecobalamin, Alpha
Lipoic Acid, Pyridoxine Hydrochloride and Folic Acid Capsules)

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: Pregabalin binds to an auxiliary subunit ($\alpha 2$ - δ protein) of voltage-gated calcium channels in the central nervous system and its efficacy has been reported in trials in diabetic neuropathy. Alpha-lipoic acid is a vitamin-like chemical called an antioxidant and is used for diabetes and nerve-related symptoms of diabetes including burning, pain, and numbness in the legs and arms. Pyridoxine hydrochloride (vitamin B6) is converted to pyridoxal phosphate which is the co-enzyme for a variety of metabolic transformations. Methylcobalamin is one of the biologically active form of vitamin B12 and acts as coenzymes in nucleic acid synthesis. Folic acid acts as coenzyme for various metabolic processes including the synthesis of nucleotides and some amino-acid conversions.

DOSAGE AND ADMINISTRATION: The required dosage should be given in either two or three divided doses. Pregabalin treatment can be started at a dose of 150 mg per day given as two or three divided doses and may be increased to 300 mg per day, after an interval of 3-7 days, and if needed, to a maximum dose of 600 mg per day after an additional 7-day interval. Dosage in patients with renal impairment (especially elderly) must be individualised according to creatinine clearance (CL_{Cr}).

CONTRAINDICATION: Hypersensitivity to the active substance, cobalt or to any of the excipients.

WARNINGS & PRECAUTIONS: Risk of weight gain in diabetic patients who may need to adjust hypoglycaemic medicinal products, hypersensitivity reactions, dizziness, somnolence, loss of consciousness, confusion, mental impairment, vision-related effects, renal failure, withdrawal symptoms, congestive heart failure, suicidal ideation and behavior, reduced lower gastrointestinal tract function, misuse, abuse or dependence, encephalopathy, decreased blood glucose levels, thiamine deficiency in case of excessive alcohol use and interference with thyroid treatment. Exercise caution while use in patients with polycythemia vera and megaloblastic anemia. Do not use in patients with Leber's disease and post-surgically to stent placement.

DRUG INTERACTIONS: Interacts with central nervous system (CNS) depressants (ethanol, oxycodone and lorazepam), chemotherapy medications, antidiabetic drugs, fosphenytoin, methotrexate, phenobarbital, phenytoin, primidone, pyrimethamine, amiodarone, levodopa and chloramphenicol when used concomitantly.

ADVERSE REACTIONS:

Nasopharyngitis, appetite increased, euphoric mood, confusion, irritability, disorientation, insomnia, libido decreased, depression, dizziness, somnolence, headache, ataxia, coordination abnormal, tremor, dysarthria, amnesia, memory impairment, disturbance in attention, paraesthesia, hypoaesthesia, sedation, balance disorder, lethargy, syncope, loss of consciousness, psychomotor hyperactivity, dyskinesia, dizziness postural, intention tremor, nystagmus, speech disorder,

hyperaesthesia, convulsions, vision blurred, diplopia, vertigo, atrioventricular block first degree, sinus arrhythmia, pulmonary oedema, vomiting, nausea, constipation, diarrhoea, flatulence, abdominal distension, dry mouth, gastrooesophageal reflux disease, stevens johnson syndrome, muscle cramp, arthralgia, back pain, pain in limb, cervical spasm, rhabdomyolysis, urinary incontinence, dysuria, renal failure, erectile dysfunction, dysmenorrhoea, breast pain, amenorrhoea, oedema peripheral, oedema, gait abnormal, fall, feeling abnormal, fatigue, increased weight, withdrawal symptoms and mouth rash.

Manufactured by:

Innova Captab Ltd.

1281/1,

Hilltop Industrial Estate Near EPIP,

Phase-1, Jharmajri, Baddi, Dist. Solan (H.P)

MARKETED BY



TORRENT PHARMACEUTICALS LTD.

IN/PREGEB FORTE 75 mg/MAY-2021/02/ABPI

(Additional information is available on request)