

Elmecob PG

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

Abbreviated Prescribing information for Elmecob PG (Pregabalin 75 mg, Methylcobalamin 750 mcg, Vitamin B6 1.5 mg, Folic Acid 0.75 mg & Benfotiamine 7.5 mg Capsules) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Pregabalin is a structural derivative of the inhibitory neurotransmitter gammaaminobutyric acid (GABA). Methylcobalamin is one of the biologically active forms of vitamin B12. Vitamin B6 is converted to pyridoxal phosphate which is the co-enzyme for a variety of metabolic transformations. Folic acid is a member of the vitamin B group which is involved in various metabolic processes. Benfotiamine is having properties of reducing the production of advanced glycation end products, and improvement of endothelial function.

INDICATION: Useful as a co-prescription in the management of: Diabetic Neuropathy, Alcohol-induced neuropathy, Vitamin-deficiency related neuropathy, Vitamin B12 induced neuropathy, Fibromyalgia, Postherpetic neuropathy, Drug and Toxin-induced neuropathy.

DOSAGE AND ADMINISTRATION: 1-2 capsules daily OR as directed by the physician.

CONTRAINDICATION: In patients with known hypersensitivity to active constituents or any of its components.

WARNINGS & PRECAUTIONS: **Pregabalin:** Diabetic patients who gain weight on pregabalin treatment may need to adjust hypoglycaemic medicinal products. Following events can occur: Hypersensitivity reactions, including cases of angioedema. Dizziness, Somnolence, Loss of consciousness, Confusion and mental impairment, Loss of vision, Visual blurring or other changes of visual acuity, Renal failure, Withdrawal symptoms: Insomnia, Headache, Nausea, Anxiety, Diarrhoea, Flu syndrome, Nervousness, Depression, Pain, Convulsion, Hyperhidrosis. Congestive heart failure, Suicidal ideation and behavior, Reduced lower gastrointestinal tract function, Abuse potential and Encephalopathy. **Methylcobalamin:** Do not exceed the stated dose. Should be given with caution in patients suffering from folate deficiency. Megaloblastic anemia is sometimes corrected by treatment with vitamin B12. But this can have very serious side effects. Do not take vitamin B12 if Leber's disease, as it can seriously harm the optic nerve, which might lead to blindness. **Vitamin B6:** Women taking oral contraceptives may exhibit increased pyridoxine requirements. **Folic acid:** Patients with vitamin B12 deficiency should not be treated with folic acid unless administered with adequate amounts of hydroxocobalamin, as it can mask the condition but the subacute irreversible damage to the nervous system will continue. Caution should be exercised for patients who may have folate dependent tumours.

DRUG INTERACTION: **Vitamin B12:** Can interact with neomycin, aminosalicic acid, histamine H2-antagonists, omeprazole, and colchicines, Potassium and Heavy drinking. **Vitamin B6:** Isoniazid, penicillamine and oral contraceptives, levodopa, phenobarbital and phenytoin. **Folic acid:** Antiepileptics (phenytoin, phenobarbital and primidone), Co-trimoxazole, Sulfasalazine and methotrexate.

ADVERSE REACTIONS: Nasopharyngitis, allergic reaction, Appetite increased, Euphoric mood, irritability, disorientation, libido decreased, Disinhibition, Ataxia, coordination abnormal, tremor, dysarthria, amnesia, memory impairment, disturbance in attention, paraesthesia, hypoaesthesia, sedation, balance disorder, lethargy, parosmia, hypokinesia, dysgraphia, diplopia, Vision loss, keratitis, oscillopsia, altered visual depth perception, mydriasis, strabismus, visual brightness, Vertigo, QT prolongation, sinus arrhythmia, throat tightness, Vomiting, constipation, flatulence, abdominal distension, dry mouth, Ascites, pancreatitis, swollen tongue, dysphagia, Stevens Johnson syndrome, Muscle cramp, arthralgia, back pain, pain in limb, cervical spasm, Rhabdomyolysis, oliguria, urinary retention, Erectile dysfunction, Amenorrhoea, breast discharge, breast enlargement, Gynaecomastia,

oedema, gait abnormal, fall, feeling drunk, feeling abnormal, fatigue, Weight increased, White blood cell count decreased, Pulmonary edema, congestive heart failure, peripheral vascular thrombosis, Polycythemia vera, exanthema, diarrhea, blood clots, itching. Peripheral neuropathies, Anorexia, abdominal distention, rash, pruritus, urticaria, dyspnea, and anaphylactic reactions.

MARKETED BY:



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(Additional information is available on request)