

PREGEB M

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

Abbreviated Prescribing information for **Pregeb M** [Pregabalin 75/150 mg& Methylcobalamin 750 mcg Capsules] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Pregabalin binds with high affinity to the alpha2-delta site (an auxiliary subunit of voltage gated calcium channels) in central nervous system tissues and it is a structural derivative of the inhibitory neurotransmitter gamma amino butyric acid (GABA) and thus produces anti-seizure effect and relief against neuropathic pain.

Methylcobalamin is involved in the synthesis of thymidine from deoxyuridine and promotes the synthesis of DNA and RNA by acting as a coenzyme in the formation of methionine from homocysteine. Methylcobalamin is reported to accelerate the synthesis of nucleic acids in bone marrow, as well as the maturation and division of erythroblasts, resulting in an increase in the production of erythrocytes. It is also reported to maintain axonal function by promoting nucleic acid and protein synthesis.

INDICATION: Combination of pregabalin and Methylcobalamin is indicated for management of neuropathic pain.

DOSAGE AND ADMINISTRATION: Treatment will be started with a capsule containing pregabalin 150mg with methylcobalamin 750mcg once daily or a capsule containing pregabalin 75mg with methylcobalamin 750mcg twice daily. The dose may be increased after an interval of 3 to7 days. Based on individual patient response and tolerability, the maximum recommended dose is four capsules of pregabalin 150mg with Methylcobalamin 750mcg per day in divided doses.

CONTRAINDICATION: In patients with known hypersensitivity to pregabalin and methylcobalamin or any of its components. Angioedema and hypersensitivity reactions have occurred in patients receiving pregabalin therapy.

WARNINGS & PRECAUTIONS: Use cautiously or stop the **pregabalin** in patient with withdrawal of antiepileptic drugs, tumorigenic potential, angioedema, hypersensitivity, Suicidal Behavior and Ideation, dizziness and somnolence, blurred vision, weight gain, peripheral edema, creatine kinase elevations, decreased platelet count, PR interval prolongation, abrupt or rapid discontinuation of pregabalin in some patients reported insomnia, nausea, headache, and diarrhea. Use cautiously or stop the **methylcobalamin** in patient with folate deficiency, Leber's disease and hereditary eye disease.

DRUG INTERACTIONS: Pregabalin: No specific drug interactions. **Methylcobalamin:** neomycin, aminosalicic acid, histamine H₂-antagonists, omeprazole, colchicine, oral contraceptives, parenteral chloramphenicol, potassium supplements, vitamin c supplements and heavy drinking.

ADVERSE REACTIONS: Dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, thinking abnormal, asthenia, accidental injury, back pain, chest pain, constipation, flatulence, peripheral edema, weight gain, hypoglycemia, neuropathy, suicidal ideation and behavior ataxia, encephalopathy, vertigo, confusion, euphoria, incoordination, tremor, abnormal gait, amnesia, nervousness, dyspnea, abnormal vision, abdominal pain, allergic reaction, fever, gastroenteritis, increased appetite, ecchymosis, arthralgia, leg cramps, myalgia, myasthenia, anxiety, depersonalization, hypertonia, hypoesthesia, libido decreased, nystagmus, paresthesia, sedation, stupor, twitching; infrequent: abnormal dreams, agitation, apathy, aphasia, hallucinations, pruritus conjunctivitis, diplopia, anorgasmia, impotence, urinary frequency, urinary incontinence, pulmonary edema, congestive heart failure, polycythemia vera, diarrhea itching; transitory exanthema, blood clots, itching and serious allergic reactions.

MARKETED BY:



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(Additional information is available on request)