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reminbay

[Pregabalin+Methylcobalamin]
75mg/500mcg Capsules

DESCRIPTION:
PREMINBAY is a combination of two medicines pregabalin (an analogue of the neurotransmitter gamma-aminobutyric acid (GABA)) and methylcobalamin (is a coenzyme type vitamin B12).

QUALITATIVE AND QUANTITATIVE COMPOSITION:
PREMINBAY (Pregabalin/Methylcobalamin) is available for oral administration as:

Each capsule contains:
Pregabalin.....75mg
Methylcobalamin..... 500mcg
(Manufacturer's Specification)

CLINICAL PHARMACOLOGY:
Mechanism of Action:
PREGABALIN:
Pregabalin reduces neuronal calcium currents by binding to the alpha-2 delta subunit of voltage gated calcium channels in CNS tissues and this particular mechanism may be responsible for effects in neuropathic pain, anxiety and other pain syndromes.

METHYLCOBALAMIN:
- Methylcobalamin is the one and only homologue of Vitamin B12 found in the brain that participates in transmethylation. Methylcobalamin is well transported to nerve cell organelles and plays the role of coenzyme and thus promoting nucleic acid protein synthesis and exerts a repairing effect on injured nerve tissues.
- Methylcobalamin normalizes axonal transport of skeletal proteins.
- Methylcobalamin promotes the synthesis of lecithin, thus promoting myelination (phospholipid synthesis).
- Methylcobalamin also restores delayed synaptic transmission and diminished neurotransmitters towards normal.

Pharmacokinetics:
PREGABALIN:
Absorption:
Following oral administration under fasting conditions, peak plasma concentrations occur within 1.5 hours. Following repeated administration, steady state is achieved within 24 to 48 hours.

Distribution:
Pregabalin does not bind to plasma proteins. The apparent volume of distribution following oral administration is approximately 0.5L/kg.

Metabolism:
Pregabalin undergoes negligible metabolism in humans.

Elimination:
Pregabalin mean elimination half-life is 6.3 hours and is eliminated from the systemic circulation primarily by renal excretion as unchanged drug.

METHYLCOBALAMIN:
Methylcobalamin substances bind to intrinsic factor; a glycoprotein secreted by the gastric mucosa and is then actively absorbed from the gastrointestinal tract.
Methylcobalamin is extensively bound (80%) to specific plasma proteins called transcobalamins; transcobalamin II appears to be involved in the rapid transport of the cobalamins to tissues.
Methylcobalamin is stored in the liver (50%), excreted in the bile and undergoes extensive enterohepatic recycling. Some of the Methylcobalamin secreted in the bile is excreted in the feces while the other part is excreted in the urine (40-80%), most of it excreted in the first 8 hours. Methylcobalamin diffuses across the placenta and also appears in breast milk.

Special Populations:
PREGABALIN:
Renal Impairment:
Pregabalin clearance is reduced in renally impaired patients. Dose adjustments are required in these patients. Pregabalin is effectively removed by hemodialysis (following 4 hours hemodialysis treatment plasma pregabalin concentrations are reduced by approximately 50%). Dose adjustments are required for patients on hemodialysis.

Elderly (Over 65 years of age):
Dose reduction may be required in patients who have age related compromised renal function.

THERAPEUTIC INDICATION:
- Management of neuropathic pain associated with diabetic peripheral neuropathy.
- Management of postherpetic neuralgia.
- Treatment of pain associated with spinal cord injury.
- As adjunctive therapy in adults with partial onset of seizures.
- Treatment of fibromyalgia syndrome (FMS).

DOSAGE AND ADMINISTRATION:
For adults, take one capsule daily or as directed by a physician.
Dose may be increased up to 300mg pregabalin/day within one week based on efficacy and tolerability.

Method of administration
PREMINBAY capsules may be taken with or without food.

Special Populations:
Renal Impairment:
Dose reduction of pregabalin may be required in these patients.

CONTRAINDICATIONS:
PREMINBAY capsules are contraindicated in patients;
- With known hypersensitive to pregabalin/Methylcobalamin or any component of this product or other B12 containing products.
- Children below the age of 18 years.

PRECAUTIONS:
PREGABALIN:
- Pregabalin should be withdrawn gradually to minimize the potential of increased seizure frequency in patients with seizure disorders.
- Pregabalin should be discontinued immediately if symptoms of angioedema, such as facial, perioral or upper airway swelling occur.
- Some diabetic patients who gain weight on pregabalin treatment may need to adjust hypoglycemic medications.
- Pregabalin should be discontinued if myopathy is diagnosed or suspected or if markedly elevated creatine kinase levels occur.
- There have been reports of congestive heart failure in some patients receiving pregabalin. These reactions are mostly seen in elderly cardiovascular compromised patients during pregabalin treatment for a neuropathic indication. Discontinuation of Pregabalin may resolve the reaction.

- Avoid alcohol consumption while on pregabalin, as it may potentiate the impairment of motor skills and sedation of alcohol.

- Pregabalin may cause dizziness and somnolence and therefore may have an influence on the ability to drive or use machines.

Withdrawal symptoms:
- After discontinuation of short-term and long-term treatment with pregabalin withdrawal symptoms have been observed in some patients. The following events have been mentioned: insomnia, headache, nausea, diarrhea, flu syndrome, nervousness, depression, pain, sweating and dizziness.

METHYLCOBALAMIN:
- Methylcobalamin should not be used for more than one month unless it is effective.
- Prolonged use of larger doses is not recommended for patients who are directly involved in handling of mercury or its compounds.
- Methylcobalamin is susceptible to photolysis. Therefore, this product should be used promptly after the package is opened, and caution should be taken so as not to expose the tablets to light/moisture.

Pregnancy and Lactation:
- **PREMINBAY** is contraindicated in pregnancy and during lactation.

DRUG INTERACTIONS:
PREGABALIN:
- Somnolence may experience when use concomitantly with CNS depressants such as opiates or benzodiazepines.
- There are some reports of respiratory failure and coma in patients taking pregabalin and other CNS depressant medications.
- Pregabalin may potentiate the effects of ethanol and lorazepam.
- Pregabalin appears to be additive in the impairment of cognitive and gross motor functions caused by oxycodone.

METHYLCOBALAMIN:
- Decreased GI tract absorption with neomycin, amino salicylic acid, H2-blockers and colchicines.
- Reduced serum concentrations with oral contraceptives.

ADVERSE REACTIONS:
The following adverse drug reactions have been reported during therapy:

PREGABALIN:
Very Common:
Dizziness, Somnolence, and Headache.

Common:
Appetite increased, tremor, memory impairment, disturbance in attention, sedation, lethargy, confusion, irritability, insomnia, vision blurred, vomiting, nausea, constipation, diarrhea, muscle cramp, muscle stiffness, gait abnormal.

Uncommon:
Anorexia, hypoglycemia, Rhinitis, nasal dryness, loss of consciousness, dizziness postural, intention tremor, eye swelling, lacrimation increased, Gastro esophageal reflux disease.

METHYLCOBALAMIN:
Generally methylcobalamin is well tolerated. However a few side effects like GI discomfort (including anorexia, nausea or diarrhea) and rash may be seen.

OVERDOSEAGE:
PREGABALIN:
Overdosage symptoms include somnolence, confusional state, agitation and restlessness. In rare occasions, coma have been reported.
Treatment of pregabalin overdose should include general supportive measures and may include haemodialysis if necessary.

INSTRUCTIONS:
- Store below 30°C.
- Protect from light & moisture.
- Keep out of reach of children.

To be sold on prescription of a registered medical practitioner.

HOW SUPPLIED:
PREMINBAY (Pregabalin+Methylcobalamin) Capsules 75mg/500mcg is available in blister pack of 30's.



Manufactured By:
SIGMA PHARMA (International Private Limited.)
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