Pregalift M™

Pregabalin and Methylcobalamin Capsules

COMPOSITION:
Each Hard Gelatin Capsule Contains:

Pregabalin	BP	75 mg
Methylcobalamin	USP	500 mcg
Excipients		q.s

Approved Colour used in Empty Capsule Shells

DESCRIPTION:
PREGALIFT M contains Pregabalin and Methylcobalamin used to treat Possesses anxiolytic, analgesic and anticonvulsant activity.
Pregabalin and Methylcobalamin is highly effective in relieving the neuropathic pain. Improves mood and reduces sleep disturbance. It gives relief relieves burning sensation, numbness, and loss of sensation & muscle cramps in diabetic neuropathy. Also used to treat Peripheral Neuropathy.

PHARMACODYNAMICS:
Pharmacotherapeutic Group: Antiepileptic, other antiepileptic.

Mechanism of Action:
Pregabalin binds to an auxiliary subunit (α2-δ protein) of voltage-gated calcium channels in the central nervous system.

Pharmacodynamics:
Pregabalin+ Methylcobalamin can reduce the release of neurotransmitters and promotes regeneration of neuronal myelin sheath. Pregabalin possess analgesic property and reduce neuropathy-related pain symptoms. Methylcobalamin is a cofactor of methionine synthase for the transfer of methyl groups to generate methionine from homocysteine. Elevated level of homocysteine is a predominant risk factor of CAD. Methionine can be converted into s-adenosylmethionine, which involve in methylation reactions related to reduction of depressive disorders. Pregabalin selectively binds to voltage-dependent calcium channel and reduce the release of substance P, glutamate, calcitonin-related peptide and norepinephrine. Contrary to other anxiolytics, Pregabalin neither binds to GABA receptors nor increase/influence GABA currents or metabolism.

Pharmacokinetic Properties:
Pregabalin:
Absorption:
Pregabalin is rapidly absorbed when administered on an empty stomach, with peak plasma concentrations occurring within one hour. Pregabalin oral bioavailability is estimated to be greater than or equal to 90% and is independent of dose. The rate of Pregabalin absorption is decreased when given with food resulting in a decrease in Cmax by approximately 25 to 30% and a delay in Tmax to approximately 2.5 hours. Administration with food, however, has no clinically significant effect on the extent of absorption.
Distribution:
In humans, the volume of distribution of Pregabalin for an orally administered dose is approximately 0.56 L/kg and is not bound to plasma proteins.
Metabolism:
Pregabalin undergoes negligible metabolism in humans. Approximately 98% of the radioactivity recovered in the urine was unchanged Pregabalin. The major metabolite is N-methyl Pregabalin.
Excretion:
Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged drug. Renal clearance of Pregabalin is 73 mL/minute
Methylcobalamin:
Methylcobalamin as adenosylcobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; in the isomerisation of methylmalonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B12 interferes with haemopoiesis and produces megaloblastic anaemia.

THERAPEUTIC INDICATIONS:
PREGALIFT M are prescribed for the treatment of:
- Possesses anxiolytic, analgesic and anticonvulsant activity.
- Possess high bioavailability (90% vs 33-66%) compared to gabapentin.
- Highly effective in relieving the neuropathic pain.
- Improves mood and reduces sleep disturbance.
- Acts as neuroprotective, promotes myelination in neurons.
- Relieves burning sensation, numbness, and loss of sensation & muscle cramps in diabetic
- neuropathy.
- Peripheral Neuropathy.
- Diabetic Neuropathy.
- Drug Induced Neuropathy

POSOLOGY AND METHOD OF ADMINISTRATION:
For adults one capsule two or three times daily or as directed by physician
PREGALIFT M Capsule is recommended to be taken with or without food.

CONTRAINDICATION:
PREGALIFT M is contraindicated in patients who are hypersensitive to Pregabalin or Methylcobalamin or any of the excipient used in the formulation.

SPECIAL WARNING AND PRECAUTION FOR USE:
PREGALIFT M may increase the risk of heart failure in patients with heart diseases. It may cause dizziness and somnolence (sleepiness). So, it might increase the risk of accidental injury in elderly patients. PREGALIFT M may also cause temporary vision problems. However, if this condition is persistent, consult your doctor immediately. Patients with diabetes who gain weight with PREGALIFT M may need a change in diabetic medicines. If you notice decreased urination while taking PREGALIFT M, inform your doctor as PREGALIFT M may cause kidney failure in some cases. It may increase suicidal tendencies, though it is rare. You may experience convulsions after discontinuing PREGALIFT M. In such cases, inform your doctor immediately.

DRUG INTERACTIONS:
Drug-drug interactions: PREGALIFT M may interact with a pain killer (oxycodone), opioids, and antianxiety drug (lorazepam), antacid (omeprazole), antibiotic (neomycin), and anti-gout medication (colchicine).
Drug-food interactions: Avoid alcohol consumption while using PREGALIFT M.
Drug-disease interactions: PREGALIFT M should be used with caution in patients with liver diseases, kidney diseases, heart problems, alcoholism, drug abuse, and suicidal tendencies.

PREGNANCY AND BREAST-FEEDING
Pregnancy:
PREGALIFT M is a category C medicine. It is not recommended for use in pregnant women unless the doctor thinks the benefits outweigh the risks.
Breast-Feeding:
PREGALIFT M Capsule is not recommended for use in breastfeeding as it may pass into breastmilk and harm your baby. Consult your doctor before taking this medicine.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
PREGALIFT M may cause dizziness and drowsiness. So, avoid driving or operating heavy machinery while using PREGALIFT M.

SIDE EFFECTS:
- Dizziness
- Drowsiness
- Headache
- Anorexia (loss of appetite)
- Nausea or vomiting
- Diarrhea
- Headache
- Sore throat
- Vision problems
- Hot sensation (burning pain)
- Diaphoresis (sweating)
- Weight gain

OVERDOSAGE:
Pregabalin
The most commonly reported adverse reactions observed when Pregabalin was taken in overdose included somnolence, confusional state, agitation, and restlessness. In rare occasions, cases of coma have been reported.
Treatment of Pregabalin overdose should include general supportive measures and may include haemodialysis if necessary.
Methylcobalamin
Overdose of a drug can be accidental. If you have taken more than the prescribed Methylcobalamin there is a chance of getting a harmful effect on your body's functions. Overdose of a medicine can lead to some medical emergency.

SHELF LIFE:
36 Months

PACKAGING
10 Capsules are packed in Alu-Alu Blister & such 3 Blisters are packed in printed carton along with pack insert.

STORAGE CONDITION:
Stored at a temperature not exceeding 30°C, Protect from light and moisture.
Keep the medicine out of reach of children.

Marketed by:

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