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For the use of Marketing Personnel of KEVA Pharmaceutical only

PRESCRIBING INFORMATION

PAGLIN 50 M FORTE

COMPOSITION

Each Capsule contains:

Pregabalin 50mg
Methylcobalamin 1500mcg

Also available as:

Paglin 50M
Paglin 75M Forte

DESCRIPTION

Pregabalin

Pregabalin is the first drug to receive approved labelling from the FDA for the treatment of painful diabetic neuropathy and post herpetic neuralgia & antiepileptic. It is structurally similar to gamma- amino butyric acid (GABA) - an inhibitory neurotransmitter.

Methylcobalamin

Methylcobalamin (Mecobalamin, MeCbl, or MeB₁₂) is a cobalamin, a form of vitamin B₁₂. It is used as a dietary supplement and to treat certain anemias. It plays important role in forming the RBCs.

PHARMACOLOGY

PHARMACOKINETICS

Pregabalin

Absorption: absorbed from the intestines by an active transport process mediated via the large neutral amino acid transporter 1 (LAT1, SLC7A5), a transporter for amino acids such as L-leucine and L-phenylalanine.

Distribution: crosses the blood–brain barrier and enters the central nervous system. However, due to its low lipophilicity, pregabalin requires active transport across the blood–brain barrier.

Metabolism: undergoes little or no metabolism

Elimination: eliminated renally in the urine, mainly in its unchanged form.

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Half life: 6.3 hours.

Renal clearance: is 73 mL/minute

Methylcobalamin

Absorption: after oral administration, vitamin B₁₂ is absorbed irregularly from the distal small intestine. Absorption depends on sufficient intrinsic factor and calcium.

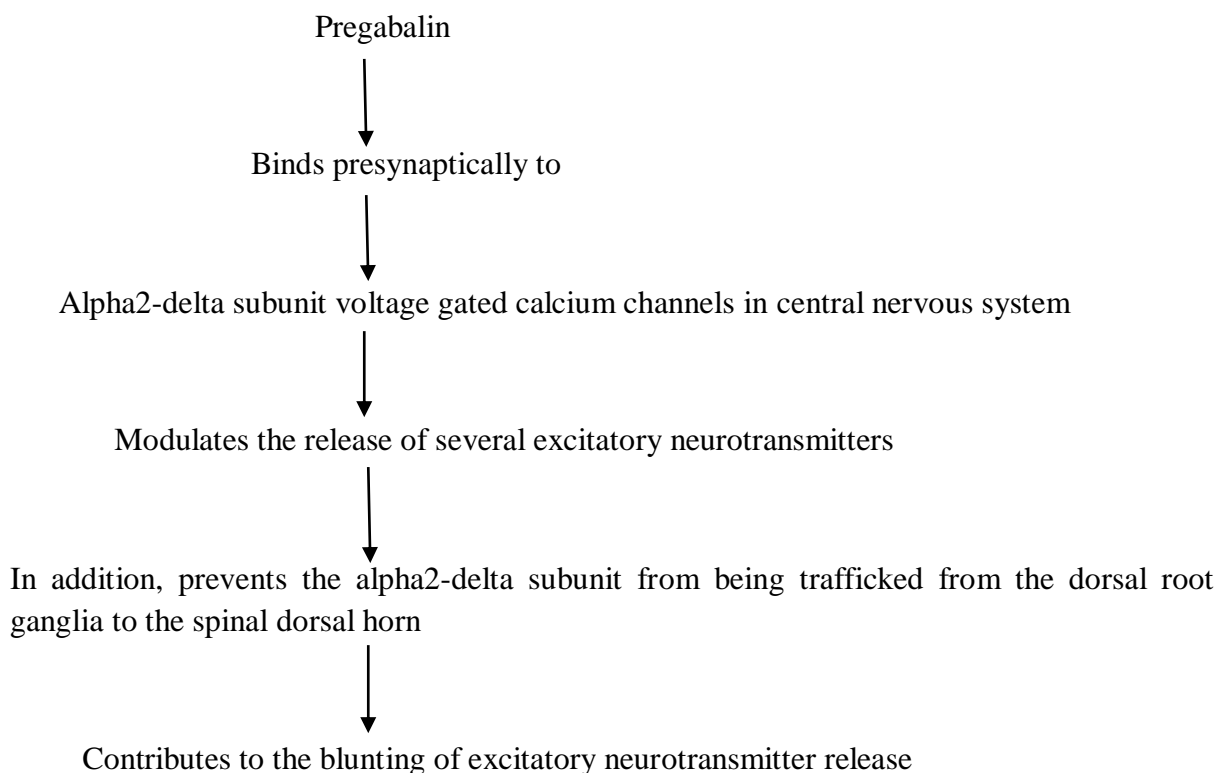
Distribution: distributed into the liver, bone marrow, and other tissues, including the placenta.

Half life: approximately 6 days

Metabolism: cyanocobalamin and hydroxocobalamin are metabolized in the liver.

Route of elimination: This drug is partially excreted in the urine.

PHARMACODYNAMICS



Methylcobalamin

Methylcobalamin contains co-enzyme with an active methyl base. It participates in transmethylation reactions and is the most active of all B₁₂ homologs in the body to nucleic

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acid, protein and lipid metabolism. It plays a role to repair damaged nerve tissue in nerve disorder involved in erythroblast maturation. Thus, acts to improve the status of the blood in Megaloblastic anemia and also on peripheral neuropathies

INDICATIONS

- Epilepsy
- Neuropathic pain
- Fibromyalgia
- Restless leg syndrome
- Generalized anxiety disorder
- Peripheral neuropathy
- Megaloblastic anemia

DOSAGES

The recommended oral dose is 1 capsule b.i.d. Patient previously on gabapentin should have a wash-out period of 1 week prior to initiation of pregabalin.

SIDE EFFECTS

Pregabalin

Headache, dizziness, sleepiness, confusion, trouble with memory, poor coordination, dry mouth, problem with vision, weight gain.

Methylcobalamin

Headache, itching, swelling, nervousness, anxiousness, involuntary or uncontrollable movements, CHF, low level of potassium in the blood, clots in the arms and legs, anaphylaxis.

CONTRAINDICATIONS

Known hypersensitivity to Pregabalin, Methylcobalamin or any of its components.

WARNINGS & PRECAUTIONS

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- It should not be given in patients with suspected vitamin B12 deficiency without first conforming diagnosis.
- Monitor blood regularly. Dose >10mcg daily may produce haematological response in patients with folate deficiency.
- Leber's disease
- Tobacco amblyopia

DRUG INTERACTIONS

Pregabalin

Opioids, benzodiazepines, barbiturates, ethanol (alcohol), ACE inhibitors may enhance the adverse/toxic effect of pregabalin. Pregabalin may enhance the fluid-retaining effect of anti-diabetic agents Thiazolidinedione.

Methylcobalamin

Chloramphenicol, oral diabetes medicine that contains metformin, cimetidine, omeprazole, lansoprazole.

PREGNANCY AND LACTATION

Pregabalin

Pregnancy category C

Evidence for the use of pregabalin during breastfeeding is limited, a single study reported extensive passage of pregabalin (dose not specified) into breast milk but low levels in the infant serum. No adverse effects have been attributed to infant exposure to gabapentin or pregabalin through the breast milk.

Methylcobalmin

Supplementation with Methylcobalamin may improve the nutritional status of pregnant women but data from clinical trials is lacking. No reports linking high doses of vitamin B₁₂ with maternal or fetal complications have been found.

Vitamin B12 has been found distributed into the milk of nursing women in concentrations similar to the maternal blood vitamin B12 concentrations. No adverse effects have been reported to date with intake of normal required doses during lactation.

PRESENTATION

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Paglin 50M is available in strip of 10 Capsules.

Each box contains 10x10's.

Paglin 50M Forte is available in strip of 10 Capsules.

Each box contains 10x10's.

Paglin 75M Forte is available in strip of 10 Capsules.

Each box contains 10x10's.

TARGETED DOCTORS

Neurologist

Othopaedics

Physician

General practitioner

COMPETITORS

S.N.	BRAND NAME	MANUFACTURER	STRENGTH	MRP
1.	Paglin 50M Forte	Pregabalin 50mg+ Methylcobalamin 1500mcg	Keva	Rs. 25/Caps
2.	Paglin 75M Forte	Pregabalin 75mg+ Methylcobalamin 1500mcg	Keva	Rs. 35/ Caps
1.	Newron 75 N Forte	Pregabalin 75mg+ Methylcobalamin 1500mcg	Quest	Rs.30/Caps
2.	Newron 50 N Forte	Pregabalin 50mg+ Methylcobalamin 1500mcg	Quest	Rs. 25/Caps
3.	Newron 75 N	Pregabalin 75mg+ Methylcobalamin 500mcg	Quest	Rs. 20/Caps
4.	Mahagaba -M	Pregabalin 75mg+ Methylcobalamin 750mcg	Qmed	Rs. 24/Caps
5.	Oromin- P	Pregabalin 75mg+ Methylcobalamin 750mcg	Corel	Rs. 24/Caps
6.	Premax plus	Pregabalin 75mg+ Methylcobalamin 750mcg	Magnus	Rs. 20/Caps
7.	Regab- M	Pregabalin 75mg+ Methylcobalamin 750mcg	Panas	Rs. 24/Caps
8.	Vegamin P-750mg	Pregabalin 75mg+ Methylcobalamin 750mcg	Vega	Rs. 24.5/ Caps
9.	PG-LIN M	Pregabalin 75mg+ Methylcobalamin 1500mcg	Maruti	Rs. 22/Caps

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10.	Renerv P1	Pregabalin 75mg+ Methylcobalamin 1500mcg	Novagenetica	Rs. 32/ Caps
11.	Vegamin P-1500mcg	Pregabalin 75mg+ Methylcobalamin 1500mcg	Vega	Rs. 32/ Caps
12.	Rejunex P	Pregabalin 75mg+ Methylcobalamin 1500mcg	Biogain	Rs. 30/Caps
13.	Neurega-ML	Pregabalin 50mg+ Methylcobalamin 500mcg	National	Rs. 20/Caps
14.	Nervilin M	Pregabalin 75mg+ Methylcobalamin 1500mcg	DJPL	Rs. 35/ Caps