

Preneu

Pregabalin BP

Composition

Preneu - 50 Capsule: Each capsule contains Pregabalin BP 50 mg.

Preneu - 75 Capsule: Each capsule contains Pregabalin BP 75 mg.

Pharmacology: Pregabalin is a structural derivative of gamma-amino-butyric acid (GABA). It does not bind directly to GABA-A, GABA-B or benzodiazepine receptors. It binds with high affinity to the $\alpha_2\text{-}\delta$ site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system tissues. Oral bioavailability of Pregabalin is 90%. Pregabalin is eliminated largely by renal excretion and has an elimination half-life of about 6 hours. Pregabalin can be taken with or without food.

Indications

Pregabalin is indicated for:

1. Management of neuropathic pain (diabetic neuropathy, postherpetic neuralgia etc.)
2. Management of fibromyalgia
3. Adjunctive therapy for partial onset of seizures/epilepsy
4. GAD (Generalized anxiety disorder)

Dosage & Administration

1. Neuropathic pain: Initially 150 mg daily in 2-3 divided doses, increased if necessary after 3-7 days to 300 mg daily in 2-3 divided doses, increased further if necessary after 7 days to max. 600 mg daily in 2-3 divided doses. Use in child and adolescents under 18 years are not recommended.
2. Fibromyalgia: The recommended dose is 300 to 450 mg daily. Dosing should begin at 150 mg daily in two divided doses and may be increased to 300 mg daily in two divided doses within 1 week based on efficacy and tolerability. Patients who do not experience sufficient benefit with 300 mg daily may be further increased 450 mg daily in two divided doses.
3. Epilepsy: Initially 150 mg daily in 2-3 divided doses, increased if necessary after 7 days to 300 mg daily in 2-3 divided doses, increased further if necessary after 7 days to max. 600 mg daily in 2-3 divided doses. Use in child and adolescents under 18 years are not recommended.
4. Generalized anxiety disorder: Initially 150 mg daily in 2-3 divided doses, increased if necessary at 7 days intervals in steps of 150 mg daily; max. 600 mg daily in 2-3 divided doses. Use in child and adolescents under 18 years are not recommended.

Contraindication: Pregabalin is contraindicated in patients with known hypersensitivity to pregabalin or any of its components.

Warning & Precautions: Abrupt or rapid discontinuation of Pregabalin may produce some symptoms including insomnia, nausea, headache and diarrhoea. So Pregabalin should be tapered gradually over a minimum of 1 week rather than discontinued abruptly. Pregabalin treatment may associate with creatine kinase elevations. It should be discontinued if myopathy is diagnosed or suspected or if markedly elevated creatine kinase levels occur.

Side Effects: Pregabalin is well tolerated but a few side effects like dizziness, somnolence and blurred vision may occur.

Use in Pregnancy & Lactation: *Pregnancy:* Pregabalin is pregnancy category-C. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. *Lactation:* Pregabalin may be secreted through the breast milk like other drugs, so it should be used in nursing women only if the benefits clearly outweigh the risks.

Use in Children & Adolescents: The safety and efficacy of Pregabalin in pediatric patients have not been established.

Drug Interactions: There are no pharmacokinetic interaction between Pregabalin and the following antiepileptic drugs: Carbamazepine, Valproic Acid, Lamotrigine, Phenytoin, Phenobarbital and Topiramate. Important pharmacokinetic interactions would also not be expected to occur between Pregabalin and commonly used antiepileptic drugs.

Overdosage: There is limited experience with overdose of Pregabalin. The highest reported accidental overdose of Pregabalin during clinical development program was 8000 mg and there was no notable clinical consequences.

Storage: Store below 30°C. Protect from light and moisture. Keep all medicines out of the reach of children.

Packing

Preneu - 50 Capsule: Each box containing 3X10's capsules in Alu- Alu blister pack.

Preneu - 75 Capsule: Each box containing 3X10's capsules in Alu- Alu blister pack.



Manufactured by:
Goodman Pharmaceuticals Ltd.
Better Health For All
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