

Pregaba[®]

Pregabalin BP

Description: Pregabalin (Pregaba[®]) is a medication originally developed for the treatment of epilepsy/seizures. It is a structural derivative of γ -aminobutyric acid (GABA) and widely used to relieve neuropathic pain, especially diabetic neuropathy, postherpetic neuralgia etc.

Mode of action: Pregabalin is a structural analogue of GABA, but does not interact with GABA_A or GABA_B receptors or influence GABA uptake. The drug's exact mechanism of action is unclear, but it may reduce excitatory neurotransmitter release by binding to the $\alpha_2-\delta$ protein subunit of voltage-gated calcium channels, widely distributed throughout the peripheral and central nervous system.

Pharmacokinetics: Oral bioavailability of pregabalin is 90%. Pregabalin is eliminated largely by renal excretion and has an elimination half-life of about 6 hrs. Administration of pregabalin with food has no clinically relevant effect on the total absorption of pregabalin. Therefore, pregabalin can be taken with or without food. Pregabalin does not bind to plasma proteins. The apparent volume of distribution of pregabalin following oral administration is approximately 0.5 L/Kg.

Composition: Pregaba[®] 25 Capsule: Each capsule contains Pregabalin BP 25 mg.

Pregaba[®] 50 Capsule: Each capsule contains Pregabalin BP 50 mg.

Pregaba[®] 75 Capsule: Each capsule contains Pregabalin BP 75 mg.

Pregaba[®] 100 Capsule: Each capsule contains Pregabalin BP 100 mg.

Pregaba[®] 150 Capsule: Each capsule contains Pregabalin BP 150 mg.

Indication: Pregabalin is indicated for:

- Management of neuropathic pain (diabetic neuropathy, postherpetic neuralgia etc.)
- Adjunctive therapy for partial onset seizures/epilepsy
- GAD (Generalised anxiety disorder)

Dosage & administration: ● 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. Child and adolescent under 18 years not recommended.
● 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. Child and adolescent under 18

years not recommended.

- Generalised anxiety disorder, initially 150 mg daily in 2-3 divided doses, increased if necessary at 7 days intervals in steps of 150 mg daily. Child and adolescent under 18 years not recommended.

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

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

Use in pregnancy and lactation: *Pregnancy:* Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. Pregabalin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation:

It is not known if pregabalin is excreted in human milk.

Precautions: Caution should be exercised when prescribing Pregabalin to patients who have angioedema, hypersensitivity, wheezing, dyspnea, rash, hives, peripheral edema, dizziness and somnolence, ophthalmological effects etc.

The safety and efficacy of Pregabalin in pediatric patients have not been established.

Drug Interaction: There are no pharmacokinetic interactions 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 the clinical development program was 8000 mg, and there were no notable clinical consequences.

Storage: Keep out of reach of children. Store in a dry place, below 25°C temperature and protected from light.

Packaging

Pregaba[®] 25 Capsule: Each carton contains 10X3 capsules in blister pack.

Pregaba[®] 50 Capsule: Each carton contains 10X3 capsules in blister pack.

Pregaba[®] 75 Capsule: Each carton contains 10X3 capsules in blister pack.

Pregaba[®] 100 Capsule: Each carton contains 10X2 capsules in blister pack.

Pregaba[®] 150 Capsule: Each carton contains 10X3 capsules in blister pack.