Pregaba® ER

Pregabalin BP

Description
Pregabalin 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 α_2-δ protein subunit of voltage-gated calcium channels, widely distributed throughout the peripheral and central nervous system.

Composition
Pregaba® ER 82.5 mg Tablet: Each Extended Release tablet contains Pregabalin BP 82.5 mg.
Pregaba® ER 165 mg Tablet: Each Extended Release tablet contains Pregabalin BP 165 mg.
Pregaba® ER 330 mg Tablet: Each Extended Release tablet contains Pregabalin BP 330 mg.

Indication
Pregaba® ER is indicated for:
• Management of Diabetic Peripheral Neuropathy (DPN)
• Management of Postherpetic neuralgia

Dosage & administration

Indication	Dosing Regimen	Initial Dose	Maximum dose
Diabetic Peripheral Neuropathy	Single dose per day	165 mg/day	330 mg/day within 1 week
Postherpetic neuralgia	Single dose per day	165 mg/day	330 mg/day within 1 week. Maximum dose 660 mg/day

Conversion from Pregabalin Capsule to Pregabalin ER Tablet:

Pregabalin Total Daily Dose (Dosed 2 or 3 times daily)	**Pregabalin ER Dose** (Dosed once a day)
75 mg	82.5 mg
150 mg	165 mg
300 mg	330 mg

Contraindications
Pregabalin is contraindicated in patients with known hypersensitivity to Pregabalin or any of its components. Angioedema and hypersensitivity reactions have been occurred in patients receiving Pregabalin therapy.

Side effects
Swelling of hands,legs and feet; suicidal thoughts or actions; dizziness and sleepiness; serious, even life-threatening allergic reactions and decreased platelet count.

Use in pregnancy and lactation
Pregnancy: Pregnancy category C.
Lactation: Small amount of Pregabalin excreted in human milk; however, the effects on breastfed infant is not known. Decide to discontinue nursing or drug according to the importance of the drug.

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

Precautions
- Discontinue Pregabalin immediately in the case of Angioedema (e.g., swelling of the throat, head and neck) and hypersensitivity reactions (e.g., hives, dyspnea and wheezing).
- Antiepileptic drugs, including Pregabalin, increase the risk of suicidal thoughts or behavior.
- Pregabalin may cause peripheral edema. Exercise caution when co-administrating Pregabalin and Thiazolidinedione antidiabetic agents.
- Pregabalin may cause dizziness, somnolence and impair patient's ability to drive or operate machinery.

Drug Interaction
No pharmacokinetic interactions were observed between Pregabalin and Erythromycin, Carbamazepine, Gabapentin, Lamotrigine, Oral Contraceptive, Phenobarbital, Phenytoin, Topiramate and Valproic acid.

Overdosage
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® ER 82.5 mg Tablet: Each carton contains 10X3 tablets in blister pack.
Pregaba® ER 165 mg Tablet: Each carton contains 10X3 tablets in blister pack.
Pregaba® ER 330 mg Tablet: Each carton contains 10X2 tablets in blister pack.