Pregaben® CR

Pregabalin Tablet

Presentation
Pregaben® CR 82.5: Each film coated tablet contains Pregabalin BP 82.5 mg.
Pregaben® CR 165: Each film coated tablet contains Pregabalin BP 165 mg.
Pregaben® CR 330: Each film coated tablet contains Pregabalin BP 330 mg.

Description
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-delta site (an auxilliary 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.

Indication and usage
Pregabalin CR is indicated for the management of-
• Neuropathic pain associated with diabetic peripheral neuropathy (DPN)
• Postherpetic neuralgia (PHN)

Dosage and administration
Neuropathic Pain Associated with Diabetic Peripheral Neuropathy: Initial dose is 165 mg once daily and increase to 330 mg once daily within 1 week based on individual patient response and tolerability. The maximum recommended dose of Pregabalin CR is 330 mg once daily.

Postherpetic Neuralgia: Initial dose is 165 mg once daily and increase to 330 mg once daily within 1 week based on individual patient response and tolerability. The maximum recommended dose of Pregabalin CR is 330 mg once daily.

Pregabalin CR should be administered once daily after an evening meal. It should be swallowed whole and should not be split, crushed, or chewed. When discontinuing Pregabalin CR, taper gradually over a minimum of 1 week.

Warning and Precautions
Discontinue Pregabalin CR immediately in patients with these symptoms-
• Angioedema
• Hypersensitivity reactions
• Seizure disorders
Pregabalin CR may increased the risk of suicidal thoughts or behavior, may also cause peripheral edema, dizziness and somnolence and impair patient's ability to operate machinery.

Contraindications
Pregabalin CR is contraindicated in patients with known hypersensitivity to Pregabalin.

Side-effects
Most common side-effects treated with Pregabalin CR are dizziness, somnolence, headache, fatigue, peripheral edema, nausea, blurred vision, dry mouth, and weight gain.

Use in specific populations
Pregnancy: May cause fetal harm. Advise of potential risk to the fetus.
Lactation: Breastfeeding is not recommended.
Pediatric patients: Safety and effectiveness of Pregabalin CR in pediatric patients have not been established.
Patient with renal impairment: Use of Pregabalin CR is not recommended for patients with creatinine clearance (CLcr) less than 30 mL/min or who are undergoing hemodialysis. Those patients should receive Pregabalin.

Drug Interactions
The interactions of Pregabalin CR with co-administration of other drugs have not been systematically evaluated. Co-administration of the prokinetic drug erythromycin with Pregabalin CR did not result in any clinically important changes in the pharmacokinetics of Pregabalin CR.

Overdosage
Overdosage of up to 8000 mg has been reported. The symptoms consist of dizziness, somnolence, blurred vision and mild diarrhoea. Pregabalin can be removed by emesis or gastric lavage.

Storage
Do not store above 30 ºC. Keep away from light and out of the reach of children.

Commercial pack
Pregaben® CR 82.5: Each box contains 3 blister strips of 10 tablets.
Pregaben® CR 165: Each box contains 3 blister strips of 10 tablets.
Pregaben® CR 330: Each box contains 5 blister strips of 6 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh