

Broklin CR

Pregabalin USP

Composition

Broklin CR 82.5 mg Tablet: Each controlled release tablet contains Pregabalin USP 82.5 mg.

Broklin CR 165 mg Tablet: Each controlled release tablet contains Pregabalin USP 165 mg.

Broklin CR 330 mg Tablet: Each controlled release tablet contains Pregabalin USP 330 mg.

Pharmacology

Pregabalin CR is a structural derivative of the inhibitory neurotransmitter gamma-amino butyric acid (GABA), it does not bind directly to GABA_A GABA_B or benzodiazepine receptors. It is inactive at serotonin and dopamine receptors and does not inhibit dopamine, serotonin or noradrenaline reuptake. Pregabalin CR binds with high affinity to the alpha₂-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system tissues. It works by decreasing the number of signals that are sent out by damaged nerve in the body.

Indication

For the management of:

- Neuropathic pain associated with Diabetic Peripheral Neuropathy (DPN)
- Post Herpetic Neuralgia (PHN)

Dose and administration

a) *Route of Administration:* Oral

Dose:

Indication	Dosing Regimen	Initial Dose	Maximum Dose
DPN Pain	Single dose per day	165 mg/day	330 mg/day within 1 week.
PHN	Single dose per day	165 mg/day	330 mg/day within 1 week Maximum dose of 660 mg/day.

Conversion dose form pregabalin to pregabalin CR

Pregabalin (dosed 2 or 3 times daily)	Pregabalin CR (dosed once a day)
75 mg/daily	82.5 mg/day
150 mg/daily	165 mg/day
225 mg/daily	247.5 mg/3x82.5 mg/once a day
300 mg/daily	330 mg/day
450 mg/daily	495 mg/3x165 mg/once a day
600 mg/daily	660 mg/2x330 mg/once a day

Contra-indication

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

Warnings & Precaution

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

Side effects

- a) *Common:* The most common side effects are dizziness, blurry vision, weight gain, fatigue, swelling of hands and feet, dry mouth & nausea.
b) *Rare:* Suicidal thoughts may be seen in a very small number of people, about 1 in 500, life threatening allergic reaction can occur.

Use in pregnancy & lactation

Pregnancy: Pregnancy Category C.

Lactation: Small amount of Pregabalin is excreted in human milk. Decide to discontinue nursing or drug according to the importance of the drug.

Use in children & adolescents

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

Geriatric use: In controlled clinical studies no overall differences in safety and efficacy were observed between geriatric patients and younger patients.

Renal impairment: Pregabalin is known to be excreted by the kidney, and the risk of toxic reactions to Pregabalin may be greater in patients with impaired renal function. Adjust the dose for elderly patients with renal impairment.

Dosage adjustment based on renal function

Creatinine Clearance (CLCr) (mL/min)	Pregabalin CR Daily Dose (mg/day)				Dose Regimen
Greater than or equal to 60	165	330	495/3x165	660/2x330	Once a day
30–60	82.5	165	247.5/3x82.5	330	Once a day
less than 30/hemodialysis	Dose with Pregabalin				

Drug interaction

a) *With Medicine:* No pharmacokinetic interactions were observed between pregabalin and erythromycin, carbamazepine, gabapentin, lamotrigine, oral contraceptive, phenobarbital, phenytoin, topiramate and valproic acid.

b) *With Food and Others:* None.

Overdose

The most commonly reported adverse events observed with Pregabalin when taken in overdose include reduced consciousness, depression/anxiety, confusional state and restlessness. Seizures and heart block have also been reported. There is no specific antidote for overdose with Pregabalin. If indicated, elimination of unabsorbed drug may be attempted by emesis or gastric lavage; Pregabalin can be removed by hemodialysis.

Storage

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

Packing

Broklin CR 82.5 mg Tablet: Each box contains 20 (2 X 10's) tablets in blister pack.

Broklin CR 165 mg Tablet: Each box contains 20 (2 X 10's) tablets in blister pack.

Broklin CR 330 mg Tablet: Each box contains 10 (1 X 10's) tablets in blister pack.

Manufactured by

ONE PHARMA LTD.

C-23-24, BSCIC I/A

Bogura, Bangladesh



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