



# Prebalin

## Pregabalin Capsule

### Presentation

**Prebalin 25:** Each capsule contains Pregabalin INN 25 mg.

**Prebalin 50:** Each capsule contains Pregabalin INN 50 mg.

**Prebalin 75:** Each capsule contains Pregabalin INN 75 mg.

**Prebalin 150:** Each capsule contains Pregabalin INN 150 mg.

### Pharmacodynamic Properties

The active substance, pregabalin is a gamma-aminobutyric acid analogue. Pregabalin binds to an auxiliary subunit ( $\alpha 2\text{-}\delta$  protein) of voltage-gated calcium channel in the central nervous system, potently displacing [ $^3\text{H}$ ]-gabapentin.

### Pharmacokinetic Properties

Pregabalin is rapidly absorbed when administered in the fasted state. Oral bioavailability is 90% and is independent of dose. Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged drug. Mean elimination half-life of Pregabalin is 6.3 hours.

### Indications

**Prebalin** is indicated for the following condition-

- ◆ Fibromyalgia
- ◆ Neuropathic pain associated with diabetic peripheral neuropathy
- ◆ Postherpetic neuralgia
- ◆ Generalized Anxiety Disorder (GAD) in adults
- ◆ As adjunctive therapy in adults with partial seizures with or without secondary generalization

### Dosage & Administration

**Prebalin** is given orally with or without food. The dose range of **Prebalin** is 150 to 600 mg per day given in either two or three divided doses. When discontinuing **Prebalin**, taper gradually over a minimum of 1 week.

**Fibromyalgia:** Adult over 18 years; The recommended dose for fibromyalgia is 300 to 450 mg/day. Dosing should begin at 75 mg two times a day (150 mg/day) and may be increased up to 150 mg two times a day (300 mg/day) within 1 week based on efficacy and tolerability.

**Neuropathic pain:** Adult over 18 years; 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 maximum 600 mg daily in 2-3 divided doses.

**Postherpetic neuralgia:** Adult over 18 years; The recommended dose for postherpetic neuralgia is 75 to 150 mg two times daily or 50 to 100 mg three times a day (150 to 300 mg/day). Dosing should begin at 75 mg two times a day or 50 mg three times a day (150 mg/day) and may be increased to 300 mg/day within 1 week based on efficacy and tolerability.

**Generalized Anxiety Disorder:** Adult over 18 years; Initially 150 mg daily in 2-3 divided doses, increased if necessary at 7-day intervals in steps of 150 mg daily; maximum 600 mg daily in 2-3 divided doses.

**Epilepsy:** Adult over 18 years; Initially 25 mg twice daily, increased at 7-day intervals in steps of 50 mg daily to 300 mg daily in 2-3 divided doses, increased further if necessary after 7 days to maximum 600 mg daily in 2-3 divided doses.

**Child & Adolescents:** Not recommended.

### Contraindications

Pregabalin is contraindicated in patients with known hypersensitivity to the active substance or to any of its excipients.

### Side Effects

Very commonly reported side effects are dizziness, somnolence, dry mouth, edema, blurred vision, weight gain or abnormal thinking.

### Precautions

Diabetic patients who gain weight on Pregabalin treatment may need to adjust hypoglycemic medications. Caution should be exercised when prescribing Pregabalin to patients who have had a previous episode of angioedema.

### In Hepatic and Renal Impairment

Pregabalin clearance is directly proportional to creatinine clearance, so dosage reduction in patients with compromised renal function must be individualized according to creatinine clearance (CL<sub>cr</sub>). No dosage adjustment is required for patients with hepatic impairment.

### Drug Interactions

Interaction may occur with CNS depressants (eg, alcohol, lorazepam, oxycodone).

### Use in Pregnancy and Lactation

Pregnancy category C. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Breast-feeding is not recommended during treatment with Pregabalin.

### Overdose

In overdoses up to 15 gm, no unexpected adverse reactions were reported. The most commonly reported adverse events in overdose are somnolence, confusional state, agitation and restlessness.

### Storage Condition

Store in a cool and dry place, away from light. Keep out of the reach of children.

### Commercial Pack

**Prebalin 25:** Each box contains 3 blister packs of 10 capsules.

**Prebalin 50:** Each box contains 3 blister packs of 10 capsules.

**Prebalin 75:** Each box contains 3 blister packs of 10 capsules.

**Prebalin 150:** Each box contains 2 blister packs of 10 capsules.

Manufactured by:

**GENERAL**  
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