



Presentation

Pregaben® 25: Each capsule contains Pregabalin INN 25 mg.
Pregaben® 50: Each capsule contains Pregabalin INN 50 mg.
Pregaben® 75: Each capsule contains Pregabalin INN 75 mg.
Pregaben® Oral Solution: Each ml oral solution contains Pregabalin INN 20 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 auxiliary 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.

Indications and Uses

- Neuralgia: (a) pain from diabetic neuropathy, (b) post herpetic neuralgia
- Fibromyalgia
- Adjunctive therapy for the treatment of partial-onset seizures in patients 1 month of age and older
- Neuropathic pain associated with spinal cord injury

Dosage and administration

Diabetic peripheral neuropathy: Initially 50 mg three times daily (150 mg/day). Maximum recommended dose is 100 mg three times daily (300 mg/day). The dose may be increased to 300 mg/day within 1 week based on efficacy and tolerability.

Post Herpetic Neuralgia: Initially 150 mg/ day in two or three divided doses. The recommended dose is 75-150 mg two times daily or 50-100 mg three times a day (150 to 300 mg/day). The dose may be increased to 300 mg/day within 1 week based on efficacy and tolerability. Maximum recommended dose is 600 mg/day in two or three divided doses.

Adjunctive Therapy for Partial-Onset Seizures in Patients 1 Month of Age and Older:

Age and Body Weight	Recommended Initial Dosage	Recommended Maximum Dosage	Dosing Regimen
Adults (17 years and older)	150 mg/day	600 mg/day	2 or 3 divided doses
Pediatric patients weighing 30 kg or more	2.5 mg/kg/day	10 mg/kg/day (not to exceed 600 mg/day)	2 or 3 divided doses
Pediatric patients weighing less than 30 kg	3.5 mg/kg/day	14 mg/kg/day	1 month to less than 4 years of age: 3 divided doses 4 years of age and older: 2 or 3 divided doses

Fibromyalgia: Initially 150 mg/ day in two divided doses. The recommended dose is 150 mg two times daily (300 mg/day). The dose may be increased to 300 mg/day within 1 week based on efficacy and tolerability. Maximum recommended dose is 450 mg/day in two divided doses

Neuropathic Pain Associated with Spinal Cord Injury: Initially 150 mg/ day in two divided doses. The recommended dose is 150 mg two times daily (300 mg/day). The dose may be increased to 300 mg/day within 1 week based on efficacy and tolerability. Maximum recommended dose is 600 mg/day in two divided doses.

Contraindication

Pregabalin is contraindicated in patients with known hypersensitivity to Pregabalin.

Side effects

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

Precautions

Abrupt or rapid discontinuation of Pregabalin may produce some symptoms including insomnia, nausea, headache and diarrhoea. So Pregabalin should be tapered gradually over a minimum of 1 week rather than discontinued abruptly. Pregabalin treatment may associate with creatine kinase elevations. It should be discontinued if myopathy is diagnosed or suspected or if markedly elevated creatine kinase levels occur.

Use in pregnancy and lactation

Pregnancy: Pregabalin is a pregnancy category-C drug. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: Pregabalin may be secreted through the breast milk like other drugs, so it should be used in nursing women only if the benefits clearly outweigh the risks.

Drug interactions

The extent of Pregabalin absorption is unaffected by gabapentin co-administration. It does not interact with other antiepileptic agents or oral contraceptive preparations.

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 °C. Keep away from light and out of the reach of children.

Commercial Pack

Pregaben® 25: Each box containing 3 blister strips of 10 capsules.
Pregaben® 50: Each box containing 3 blister strips of 10 capsules.
Pregaben® 75: Each box containing 3 blister strips of 10 capsules.
Pregaben® Oral Solution: Each bottle contains 100 ml of Pregabalin oral solution.