

Broklin

Pregabalin USP

Presentation

Broklin 50 Capsule: Each capsule contains Pregabalin USP 50 mg.

Broklin 75 Capsule: Each capsule contains Pregabalin USP 75 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
- Partial seizure / epilepsy: Pregabalin is also indicated as adjunctive therapy for adult patients with partial onset seizures
- Generalised anxiety disorder
- Neuropathic pain associated with spinal cord injury

Dosage and administration

Neuropathic pain

Initially 150 mg daily in 2 divided doses, increased if necessary after 3-7 days to 300 mg daily in 2 divided doses, increased further if necessary after 7 days to maximum 600 mg daily in 2 divided doses.

Post herpetic neuralgia

The recommended dose of pregabalin is 75 to 150 mg two times a day. Dosing should begin at 75 mg two times a day and may be increased to 300 mg/day within 1 week based on efficacy and tolerability.

Fibromyalgia

The recommended dose of pregabalin for fibromyalgia is 300 to 450 mg daily in 2 divided doses.

Epilepsy

Initially 150 mg daily in 2 divided doses, increased if necessary after 7 days to 300 mg in 2 divided doses, increased further if necessary after 7 days to maximum 600 mg daily in 2 divided doses.

Generalised anxiety disorder

Initially 150 mg daily in 2 divided doses, increased if necessary after 7 days to 300 mg in 2 divided doses, increased further if necessary after 7 days to maximum 600 mg daily in 2 divided doses.

Neuropathic pain associated with spinal cord injury

The recommended dose is 150 to 600 mg /day. Initially 75 mg b.i.d; may be increased to 150 mg b.i.d (300 mg /day) within 1 week . Maximum 300 mg b.i.d (600 mg/day)

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.

Pediatric Use

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

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

Store below 30° C temperature and cool and dry place, away from light. Keep out of the reach of children.

Commercial Pack

Broklin 50 Capsule: Each box containing 3 blister of 10 capsules.

Broklin 75 Capsule: Each box containing 2 blister of 10 capsules.