Pegaron™

Pregabalin

Jenphar Bangladesh | جنفار بنغلاديش

Composition:
Pegaron™ 25 mg Capsule: Each capsule contains Pregabalin USP 25 mg.
Pegaron™ 50 mg Capsule: Each capsule contains Pregabalin USP 50 mg.
Pegaron™ 75 mg Capsule: Each capsule contains Pregabalin USP 75 mg.

Pharmacology:
Pregabalin 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 receptor. It is inactive at serotonin and dopamine receptors and does not inhibit dopamine, serotonin, or noradrenaline reuptake. Pregabalin binds with high affinity to the $alpha_2$-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system tissues. Pregabalin's oral bioavailability is equal or more than 90% and is independent of dose. It is eliminated from the systemic circulation primarily by renal excretion as unchanged drug with a mean elimination half-life of 6.3 hours in subjects with normal renal function.

Indication:
Pregabalin is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy and management of post herpetic neuralgia. It is also indicated for the adjunctive therapy for partial onset seizures in patients 1 month of age and older. It can be used for the management of fibromyalgia & neuropathic pain associated with spinal cord injury.

Dose & administration:
Route of Administration: By mouth

Neuropathic pain associated with diabetic peripheral neuropathy: The maximum recommended dose of Pregabalin is 100 mg three times a day (300 mg/day) in patients with creatinine clearance of at least 60 ml/min. Dosing should begin at 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.

Safety & effectiveness in pediatric patients have not been established.

Post herpetic neuralgia: The recommended dose of Pregabalin is 75 to 150 mg two times a day, or 50 to 100 mg three times a day (150 to 300 mg/day) in patients with creatinine clearance of at least 60 ml/min. 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.

Safety & effectiveness in pediatric patients have not been established.

Adjunctive Therapy for Partial Onset Seizures:

Age & Body Weight	Recommended Initial Dosage (2 or 3 divided doses)	Recommended Maximum Dosage
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 11 kg to 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

Safety and effectiveness in pediatric patients below the age of 1 month have not been established.

Management of Fibromyalgia: The recommended dose of Pregabalin 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 to 150 mg two times a day (300-mg/day) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient benefit with 300 mg/day may be further increased to 225 mg two times a day (450 mg/day).

Safety & effectiveness in pediatric patients have not been established.

Neuropathic Pain Associated with Spinal Cord Injury: The recommended dose range of Pregabalin for the treatment of neuropathic pain associated with spinal cord injury is 150 to 600 mg/day. The recommended starting dose is 75 mg two times a day (150 mg/day). The dose may be increased to 150 mg two times a day (300 mg/day) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient pain relief after 2 to 3 weeks of treatment with 150 mg two times a day and who tolerate Pregabalin may be treated with up to 300 mg two times a day.

Safety & effectiveness in pediatric patients have not been established.

Pregabalin capsules can be taken without regards to meals.

Contra-indication:
Pregabalin is contraindicated in patients with known hypersensitivity to Pregabalin or any of its components.

Warning & precaution:
Discontinuation of Pregabalin without tapering may produce insomnia, nausea, headache and diarrhea. So, it should be tapered gradually over a minimum of 1 week rather than discontinued abruptly. Creatinine kinase may be elevated if treated with Pregabalin. It should be discontinued rapidly if myopathy is diagnosed or suspected or if creatinine kinase is elevated markedly.

Side effects:
The most common side effects include dizziness, somnolence, dry mouth, edema, blurred vision, weight gain and abnormal thinking.

Use in pregnancy and lactation:
Pregnancy: May cause fetal harm.
Lactation: Breastfeeding is not recommended.

Use in children & adolescents:
See Dosage & administration

Drug interaction:
Specifically, there are no pharmacokinetic interactions between pregabalin and the following antiepileptic drugs: carbamazepine, valproic acid, lamotrigine, phenytoin, phenobarbital, and topiramate.

Overdose:
There is no specific antidote for overdose with Pregabalin. If indicated, elimination of unabsorbed drug may be attempted by emesis or gastric lavage. Standard hemodialysis procedures result in significant clearance of pregabalin (approximately 50% in 4 hours).

Storage:
Keep out of the reach of children. Store in a cool and dry place below 30^0 C, protect from light.

Packing:
Pegaron™ 25 mg Capsule: Each box contains 30 capsules in Alu-Alu blister packs.
Pegaron™ 50 mg Capsule: Each box contains 30 capsules in Alu-Alu blister packs.
Pegaron™ 75 mg Capsule: Each box contains 30 capsules in Alu-Alu blister packs.

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Manufactured by:
Jenphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh.