

Pregan/Pregan ER

Pregabalin BP

Composition

Pregan 25: Each capsule contains Pregabalin BP 25 mg.

Pregan 50: Each capsule contains Pregabalin BP 50 mg.

Pregan 75: Each capsule contains Pregabalin BP 75 mg.

Pregan ER 82.5: Each extended release tablet contains Pregabalin BP 82.5 mg.

Pregan ER 165: Each extended release tablet contains Pregabalin BP 165 mg.

Pharmacology

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.

Indication

Pregabalin Capsule- ● Neuralgia: (a) Pain from diabetic neuropathy, (b) Post-herpetic neuralgia ● Fibromyalgia ● Partial seizure/Epilepsy.

Pregabalin ER Tablet- ● Diabetic peripheral neuropathy ● Post-herpetic neuralgia

Dosage & Administration

Pregabalin Capsule:

Indication	Dosing Regimen	Initial Dose	Maximum Dose
Neuropathic pain	2 or 3 divided doses per day	150 mg	600 mg
Epilepsy	2 or 3 divided doses per day	50 mg	600 mg
Generalized anxiety disorder	2 or 3 divided doses per day	150 mg	600 mg
Fibromyalgia	2 or 3 divided doses per day	150 mg	450 mg

Pregabalin ER Tablet: **Pregabalin ER tablet should be administered once daily after an evening meal. It should be swallowed whole and should not be split, crushed or chewed.**

Indication	Dosing Regimen	Initial Dose	Maximum Dose
Diabetic peripheral neuropathy	Once daily	165 mg	330 mg
Post-herpetic neuralgia	Once daily	165 mg	660 mg

Conversion from Pregabalin capsules to Pregabalin ER tablets

Pregabalin (Total dose 2 or 3 times daily)	Pregabalin ER (Dose once a day)
75 mg/daily	82.5 mg/daily
150 mg/daily	165 mg/daily
300 mg/daily	330 mg/daily

Or as directed by the physician.

Contraindication

Pregabalin is contraindicated in patients with known hypersensitivity to Pregabalin.

Warning & Precaution

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 be 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.

Side Effects

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

Use in Pregnancy & 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.

Use in Children & Adolescents

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

Drug Interaction

In vitro and in vivo studies, it has been showed that Pregabalin is unlikely to be involved in significant pharmacokinetic drug interactions. Specifically, there are no pharmacokinetic interactions between Pregabalin and the following antiepileptic drugs: carbamazepine, valproic acid, lamotrigine, phenytoin, phenobarbital, and topiramate. Important pharmacokinetic interactions are also not expected to occur between Pregabalin and commonly used antiepileptic drugs.

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

Packing

Pregan 25 : Each box contains 3 X 10 capsules in Alu-Alu blister strips with an insert.

Pregan 50 : Each box contains 5 X 6 capsules in Alu-Alu blister strips with an insert.

Pregan 75 : Each box contains 5 X 6 capsules in Alu-Alu blister strips with an insert.

Pregan ER 82.5 : Each box contains 2 X 10 tablets in Alu blister strips with an insert.

Pregan ER 165 : Each box contains 2 X 10 tablets in Alu blister strips with an insert.

Manufactured by:

Navana Pharmaceuticals Ltd.

Rupshi, Rupganj, Narayanganj, Bangladesh

NCLT0746_12-23_01

 **NAVANA PHARMA**