

# Gabatec

## Pregabalin USP

### Description

Gabatec (Pregabalin) is a medication originally developed for the treatment of epilepsy/seizures. It is a structural derivative of GAMA-aminobutyric acid (GABA) and widely used to relieve neuropathic pain, especially diabetic neuropathy, postherpetic neuralgia etc.

### Composition

**Gabatec 25:** Each capsule contains Pregabalin USP 25 mg.  
**Gabatec 50:** Each capsule contains Pregabalin USP 50 mg.  
**Gabatec 75:** Each capsule contains Pregabalin USP 75 mg.  
**Gabatec 100:** Each capsule contains Pregabalin USP 100 mg.  
**Gabatec 150:** Each capsule contains Pregabalin USP 150 mg.

### Mode of Action

Pregabalin is a structural analogue of GABA, but does not interact with GABA<sub>A</sub> or GABA<sub>B</sub> receptors or influence GABA uptake. The drug's exact mechanism of action is unclear, but it may reduce excitatory neurotransmitter release by binding to the  $\alpha 2\text{-}\delta$  protein subunit of voltage-gated calcium channels, widely distributed throughout the peripheral and central nervous system.

### Pharmacokinetics

Oral bioavailability of Pregabalin is 90%. Pregabalin is eliminated largely by renal excretion and has an elimination half-life of about 6 hrs. Administration of Pregabalin with food has no clinically relevant effect in the total absorption of Pregabalin. Therefore, Pregabalin can be taken with or without food. Pregabalin does not bind to plasma proteins. The apparent volume of distribution of Pregabalin following oral administration is approximately 0.5 L/Kg.

### Indications

Pregabalin is indicated for:  
Management of neuropathic pain (diabetic neuropathy, postherpetic neuralgia etc.)  
Adjunctive therapy for partial onset seizure/epilepsy  
GAD (Generalised Anxiety Disorder)

### Dosage and Administration

**Neuropathic pain:** 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 max. 600 mg daily in 2-3 divided doses. Child and adolescent under 18 years not recommended.

**Epilepsy:** Initially 150 mg daily in 2-3 divided doses, increased if necessary after 7 days to 300 mg daily in 2-3 divided doses, increased further if necessary after 7 days to max. 600 mg daily in 2-3 divided doses. Child and adolescent under 18 years not recommended.

**Generalised anxiety disorder:** Initially 150 mg daily in 2-3 divided doses, increased if necessary at 7 days intervals in steps of 150 mg daily. Child and adolescent under 18 years not recommended.

### Contraindications

Pregabalin is contraindicated in patients with known hypersensitivity to Pregabalin or any of its components.

### Side Effects

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

### Use in pregnancy & lactation

Pregnancy: Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. Pregabalin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is not known if Pregabalin is excreted in human milk.

### Precautions

Caution should be exercised when prescribing Pregabalin to patients who have angioedema, hypersensitivity, wheezing, dyspnea, rash, hives, peripheral edema, dizziness and somnolence, ophthalmological effects etc.

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

### Drug Interactions

There are no pharmacokinetic interactions between pregabalin and the following antiepileptic drugs: carbamazepine, valproic acid, lamotrigine, phenytoin, phenobarbital, and topiramate. Important pharmacokinetic interactions would also not be expected to occur between Pregabalin and commonly used antiepileptic drugs.

### Overdose

There is limited experience with overdose of Pregabalin. The highest reported accidental overdose of pregabalin during the clinical development program was 8000 mg, and there were no notable clinical consequences.

### Storage

Do not store above 30° C. Protect from light. Keep medicine out of reach of children.

### Packaging

**Gabatec 25:** Each box contains 3x10's capsules in blister pack.  
**Gabatec 50:** Each box contains 3x10's capsules in blister pack.  
**Gabatec 75:** Each box contains 3x10's capsules in blister pack.  
**Gabatec 100:** Each box contains 3x8's capsules in blister pack.  
**Gabatec 150:** Each box contains 3x8's capsules in blister pack.

Manufactured by



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