

Gablin™

(Pregabalin)

Capsule

COMPOSITION

Gablin Capsule 25 mg:

Each Hard gelatin capsule contains:
Pregabalin (USP) 25 mg.

Product Specs.: BP

Gablin Capsule 50 mg:

Each Hard gelatin capsule contains:
Pregabalin (USP) 50 mg.

Product Specs.: BP

Gablin Capsule 75 mg:

Each Hard gelatin capsule contains:
Pregabalin (USP) 75 mg.

Product Specs.: BP

Gablin capsule 100 mg:

Each Hard gelatin capsule contains:
Pregabalin (USP) 100 mg.

Product Specs.: BP

Gablin Capsule 150 mg:

Each Hard gelatin capsule contains:
Pregabalin (USP) 150 mg.

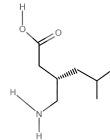
Product Specs.: BP

Gablin Capsule 300 mg:

Each Hard gelatin capsule contains:
Pregabalin (USP) 300 mg.

Product Specs.: BP

DESCRIPTION: Pregabalin is described chemically as (S)-3-(aminomethyl)-5-methylhexanoic acid. The molecular formula is C₈H₁₅NO₂ and the molecular weight is 159.23. The chemical structure of pregabalin is:



CLINICAL PHARMACOLOGY:

Mechanism of Action:

Gablin binds with high affinity to the alpha2-delta subunit of voltage-gated calcium channels in the CNS. Its exact mechanism is unclear; however, it likely reduces calcium-dependent release of pain-related neurotransmitters.

Pharmacokinetics:

Absorption and distribution:

Pregabalin is well absorbed after oral administration. Under fasting conditions, peak plasma concentrations occur within 1.5 hours. Pregabalin oral bioavailability is ≥90% and is independent of dose. Food doesn't affect absorption. It does not bind to plasma proteins. The apparent volume of distribution following oral administration is approximately 0.5 L/kg.

Metabolism and elimination:

Pregabalin undergoes negligible metabolism in humans. It is eliminated primarily by renal excretion as unchanged drug with a mean elimination half-life of 6.3 hours in subjects with normal renal function.

Special Populations:

Renal impairment and hemodialysis: Pregabalin clearance is nearly proportional to creatinine clearance (Cl_{cr}). Dosage reduction in patients with renal dysfunction is necessary. Pregabalin is effectively removed from plasma by hemodialysis. Following a 4-hour hemodialysis treatment, plasma pregabalin concentrations are reduced by approximately 50%. For patients on hemodialysis, dosing must be modified.

INDICATIONS AND USAGE:

Gablin is indicated for management of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, adjunct therapy for adult patients with partial onset seizures, fibromyalgia & neuropathic pain associated with spinal cord injury.

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DOSAGE AND ADMINISTRATION:

For all indications, begin dosing at 150 mg/day. When discontinuing GABLIN, taper gradually over minimum of 1 week.

CONTRAINDICATIONS:

GABLIN is contraindicated in patients with known hypersensitivity to pregabalin or any of its components. Angioedema and hypersensitivity reactions have occurred in patients receiving pregabalin therapy.

WARNINGS AND PRECAUTIONS:

Angioedema (e.g., swelling of the throat, head and neck) can occur, and may be associated with life-threatening respiratory compromise requiring emergency treatment. Discontinue GABLIN immediately in these cases. Hypersensitivity reactions (e.g. hives, dyspnea, and wheezing) can occur. Discontinue GABLIN immediately in these patients. Increased seizure frequency may occur in patients with seizure disorders if GABLIN is rapidly discontinued. Withdraw GABLIN gradually over a minimum of 1 week. Antiepileptic drugs, including GABLIN, increase the risk of suicidal thoughts or behavior. GABLIN may cause peripheral edema. Exercise caution when co-administering GABLIN and thiazolidinedione antidiabetic agents. GABLIN may cause dizziness and somnolence and impair patients' ability to drive or operate machinery.

DRUG INTERACTIONS:

Gablin has no pharmacokinetic interactions with common antiepileptic drugs. While co-administration with oxycodone, lorazepam, or alcohol shows no interaction, additive effects on cognition and motor function may occur, without significant impact on respiration.

Indication	Dosing Regimen	Maximum Dose
Diabetic Peripheral Neuropathic Pain	3 divided doses/day	300 mg/day within 1 week
Postherpetic Neuralgia	2 or 3 divided doses/day	300 mg/day within 1 week; max 600 mg/day
Adjunctive Therapy for Partial Onset Seizures	2 or 3 divided doses/day	Max 600 mg/day
Fibromyalgia	2 divided doses/day	300 mg/day within 1 week; max 450 mg/day
Neuropathic Pain Associated with Spinal Cord Injury	2 divided doses/day	300 mg/day within 1 week; max 600 mg/day

USE IN SPECIFIC POPULATIONS:

Pregnancy: Category C

There are no adequate and well-controlled studies with GABLIN in pregnant women. Use GABLIN during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: Small amounts of pregabalin have been detected in the milk of lactating women. It is important to decide whether to discontinue nursing or drug, taking into account the importance of drug to the mother.

Pediatric use: The safety and efficacy of pregabalin in pediatric patients have not been established.

Geriatric use: Adjust the dose for elderly patients with renal impairment.

ADVERSE AND REACTIONS:

Most common adverse reactions are dizziness, somnolence, dry mouth, edema, blurred vision, weight gain and thinking abnormal (primarily difficulty with concentration/attention) during the clinical trial experience.

Post marketing experience: The following adverse reactions have been identified during post approval use of pregabalin.

Nervous System Disorders: Headache

Gastrointestinal Disorders: Nausea, Diarrhea

Reproductive System and Breast Disorders: Gynecomastia, Breast Enlargement.

There are also post marketing reports of respiratory failure and coma in patients taking pregabalin and other CNS depressant medications.

OVERDOSAGE:

There is no specific antidote for GABLIN overdose. Supportive care, including airway management and monitoring, is recommended. Hemodialysis may be considered, especially in renal impairment, as it clears about 50% of pregabalin in 4 hours. Consult Poison Control for guidance.

INSTRUCTIONS:

- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

- Gablin Capsule 25 mg** : Pack of 2x7 capsules.
- Gablin Capsule 50 mg** : Pack of 2x7 capsules.
- Gablin Capsule 75 mg** : Pack of 2x7 capsules.
- Gablin Capsule 100 mg** : Pack of 2x7 capsules.
- Gablin Capsule 150 mg** : Pack of 2x7 capsules.
- Gablin Capsule 300 mg** : Pack of 2x7 capsules.

Manufactured by:

CCL Pharmaceuticals (Pvt.) Ltd.

Plot No. 710, Sundar Industrial Estate, Raiwind Road Lahore, Pakistan.

FOR FURTHER INFORMATION PLEASE CONTACT:



Manufactured for:
CCL Pharmaceuticals (Pvt.) Ltd.
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔