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Gablin®

(Pregabalin) Capsule

گیبلن

COMPOSITION
Gablin Capsule 25 mg:
Each capsule contains:
Pregabalin ..... 25 mg.

Product Specs.: CCL Pharmaceuticals

Gablin Capsule 50 mg:
Each capsule contains:
Pregabalin ..... 50 mg.

Product Specs.: CCL Pharmaceuticals

Gablin Capsule 75 mg:
Each capsule contains:
Pregabalin ..... 75 mg.

Product Specs.: CCL Pharmaceuticals

Gablin capsule 100 mg:
Each capsule contains:
Pregabalin ..... 100 mg.

Product Specs.: CCL Pharmaceuticals)

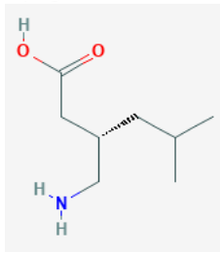
Gablin Capsule 150 mg:
Each capsule contains:
Pregabalin ..... 150 mg.

Product Specs.: CCL Pharmaceuticals

Gablin Capsule 300 mg:
Each capsule contains:
Pregabalin ..... 300 mg.

Product Specs.: CCL Pharmaceuticals

DESCRIPTION:
Pregabalin is described chemically as (S)-3-(aminomethyl)-5-methylhexanoic acid. The molecular formula is $C_8H_{17}NO_2$ and the molecular weight is 159.23. The chemical structure of pregabalin is:



CLINICAL PHARMACOLOGY:
Mechanism of Action:
Gabalin binds with high affinity to the alpha2-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system tissues. Although the mechanism of action of pregabalin has not been fully elucidated, but pregabalin has been shown to reduce calcium-dependent release of pro-nociceptive neurotransmitters in the spinal cord, possibly by disrupting alpha2-delta containing-calcium channel trafficking and/or reducing calcium currents.
Pharmacokinetics: Pregabalin is well absorbed after oral administration, is eliminated largely by renal excretion, and has an elimination half-life of about 6 hours.
Absorption and Distribution:
Following oral administration of GABLIN capsules under fasting conditions, peak plasma concentrations occur within 1.5 hours. Pregabalin oral bioavailability is greater than or equal to 90% and is independent of dose. Administration of pregabalin with food has no clinically relevant effect on the total absorption of pregabalin. Pregabalin does not bind to plasma proteins. The apparent volume of distribution of pregabalin following oral administration is approximately 0.5 L/kg. Pregabalin is a substrate for system L transporter which is responsible for the transport of large amino acids across the blood brain barrier.
Metabolism and Elimination:
Pregabalin undergoes negligible metabolism in humans, approximately 90% of the administered dose recovered in the urine as unchanged pregabalin.
Pregabalin 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.
Pharmacokinetics in Special Populations:
Race: The pharmacokinetics of pregablin were not significantly affected by race.
Gender: GABLIN drug exposure is similar between genders.
Renal Impairment and Hemodialysis: Pregabalin clearance is nearly proportional to creatinine clearance (Clcr). 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.
Elderly Population: Pregabalin oral clearance tend to decrease with increasing age. This decrease in pregabalin oral clearance is consistent with age-related decreases in CLcr. Reduction of pregabalin dose may be required in patients who have age-related compromised renal function.
Pediatric Population: In the pediatric age group of 12 years of age and older, systemic exposure of pregabalin is similar to adults at any given dose of GABLIN.

INDICATION	Dosing Regimen	Maximum Dose
Diabetic peripheral Neuropathic Pain	3 divided doses/ day	300 mg/day within 1 week
Postherpatic Neuralgia	2 or 3 divided doses/day	300 mg/day within 1 week. Maximum dose of 600 mg/day.
Adjunctive Therapy for Adult Patients with Partial Onset Seizures	2 or 3 divided doses/day	Maximum dose of 600 mg/day.
Fibromyalgia	2 divided doses/day	300 mg/day within 1 week. Maximum dose of 450 mg/day.
Neuropathic Pain Associated with Spinal Cord Injury	2 divided doses/day	300 mg/day within 1 week. Maximum dose of 600 mg/day.

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INDICATIONS AND USAGE:
GABLIN is indicated for:
- Management of neuropathic pain associated with diabetic peripheral neuropathy
- Management of postherpetic neuralgia
- Adjunctive therapy for adult patients with partial onset seizures
- Management of fibromyalgia
- Management of neuropathic pain associated with spinal cord injury

DOSAGE AND ADMINISTRATION:
For all indications, begin dosing at 150 mg/day. GABLIN is given orally with or without food. When discontinuing GABLIN, taper gradually over a minimum of 1 week. Dose should be adjusted in patients with reduced renal function.
Dose Modification Recommendations: Because GABLIN is eliminated primarily by renal excretion, adjust the dose in patients with reduced renal function.

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:
Since GABLIN is predominantly excreted unchanged in the urine, undergoes negligible metabolism in humans (less than 2% of a dose recovered in urine as metabolites), and does not bind to plasma proteins, its pharmacokinetics are unlikely to be affected by other agents through metabolic interactions or protein binding displacement. Specifically, 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 GABLIN and commonly used antiepileptic drugs. Multiple oral doses o pregablin were co-administered with oxycodone, lorazepam, or ethanol. Although no pharmacokinetic interactions were seen, additive effects on cognitive and gross motor functioning were seen when GABLIN was co-administered with these drugs. No clinically important effects on respiration were seen.

USE IN SPECIFIC POPULATIONS:
Pregnancy:
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 go r 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: No overall differences in safety and efficacy were observed between these patients and younger patients. Because GABLIN is eliminated primarily by renal excretion, 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 pregablin. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
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 overdose with GABLIN. If indicated, elimination of unabsorbed drug may be attempted by emesis or gastric lavage; observe usual precautions to maintain the airway. General supportive care of the patient is indicated including monitoring of vital signs and observation of the clinical status of the patient. Contact a Certified Poison Control Center for up-to-date information on the management of overdose with GABLIN. Although hemodialysis has not been performed in the few known cases of overdose, it may be indicated by the patient's clinical state or in patients with significant renal impairment. Standard hemodialysis procedures result in significant clearance of pregabalin (approximately 50% in 4 hours). Although hemodialysis has not been performed in the few known cases of overdose, it may be indicated by the patient's clinical state or in patients with significant renal impairment. Standard hemodialysis procedures result in significant clearance of pregabalin (approximately 50% in 4 hours).

INSTRUCTIONS:
Store below 30°C. Protect from heat, sunlight and 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.

ہدایات:

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

FOR FURTHER INFORMATION PLEASE CONTACT.

Manufactured by:
CCL Pharmaceuticals (Pvt.) Ltd.
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