



Gabium

(P r e g a b a l i n)

CAPSULES

DESCRIPTION

Pregabalin molecular formula is $C_8H_{17}NO_2$ and the molecular weight is 159.23. Pregabalin is described chemically as (S)-3-(aminomethyl)-5-methylhexanoic acid.

COMPOSITION

GABIUN 50mg capsules:

Each capsule contains: Pregabalin (B.P).....50mg

GABIUN 75mg capsules:

Each capsule contains: Pregabalin (B.P).....75mg

GABIUN 100mg capsules:

Each capsule contains: Pregabalin (B.P).....100mg

CLINICAL PHARMACOLOGY

MODE OF ACTION:

Pregabalin binds with high affinity to the alpha2-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system tissues. Still the mechanism of action of pregabalin is unknown, results with genetically modified mice and with compounds structurally related to pregabalin (such as gabapentin) suggest that binding to the alpha2-delta subunit may be involved in pregabalin's antinociceptive and anti-seizure effects in animal models. In vitro, pregabalin reduces the calcium-dependent release of several neurotransmitters, possibly by modulation of calcium channel function.

While pregabalin is a structural derivative of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA), it does not bind directly to $GABA_A$, $GABA_B$, or benzodiazepine receptors, does not augment $GABA_A$ responses in cultured neurons, does not alter rat brain GABA concentration or have acute effects on GABA uptake or degradation. However, in cultured neurons prolonged application of pregabalin increases the density of GABA transporter protein and increases the rate of functional GABA transport. Pregabalin does not block sodium channels, is not active at receptors, and does not alter activity. It is inactive at serotonin and dopamine receptors & does not inhibit reuptake of serotonin, dopamine, or noradrenaline.

INDICATIONS

PREGABALIN IS INDICATED FOR:

Neuropathic pain associated with diabetic peripheral neuropathy,

postherpetic neuralgia, adjunctive therapy for adult patients with partial onset seizures and fibromyalgia.

CONTRAINDICATIONS

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

PRECAUTIONS

Angioedema, Hypersensitivity, Withdrawal of Antiepileptic Drugs (AEDs), Peripheral Edema, Dizziness and Somnolence, Weight Gain, Ophthalmological Effects, Creatine Kinase Elevations, Decreased Platelet Count PR Interval Prolongation, Nonclinical toxicology: Carcinogenesis, Mutagenesis, Impairment of Fertility.

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

SIDE EFFECTS

The most common side effects of Pregabalin in 1 out of 10 people are: Tiredness and dizziness.

Side effects of Pregabalin in 1 out of 100 people are:

Increased appetite, feeling of confusion, changes in sexual interest, irritability, distribution in attention, clumsiness, memory impairment, tremor, difficulty with speaking, tingling feeling, blurred vision, double vision, vertigo, dry mouth, constipation, vomiting, flatulence, difficulties with erection, swelling of the extremities, feeling drunk, abnormal style of walking and weight gain.

OVERDOSAGE

There is no specific treatment or antidote for overdose with pregabalin. If indicated, elimination of unabsorbed drug may be attempted by emesis or gastric lavage, usual precautions should be observed 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. A Certified should be contacted for up-to-date information on the management of overdose with pregabalin.

DOSAGE AND ADMINISTRATION

Neuropathic Pain Associated with Diabetic Peripheral Neuropathy:

The maximum recommended dose of pregabalin is 100mg three times a day (300mg/day) in patients with creatinine clearance of at least 60 mL/min. Dosing should start at 50 mg 3 times a day (150 mg/day) and may be gradually increased to 300 mg/day within 1 week based on efficacy and tolerability. Since pregabalin is eliminated primarily by renal excretion, the dose should be adjusted for patients with reduced renal function.

POSTHERPETIC NEURALGIA

Dose of pregabalin is 75 to 150mg two times a day, or 50 to 100mg 3 times a day (150 to 300mg/day) in patients with creatinine clearance of at least 60 mL/min. Dose should be started at 75mg 2 times a day, or 50mg 3 times a day (150mg/day) and may be increased to 300mg/day within 1 week based on efficacy and tolerability. Patients who does not have sufficient pain relief following 2 to 4 weeks of treatment with 300mg/day, and who are able to tolerate pregabalin, may be treated with up to 300mg two times a day, or 200mg three times a day (600 mg/day).

Adjunctive Therapy for Adult Patients with Partial Onset Seizures:

Dose of pregabalin 150 to 600mg/day has been shown to be effective as adjunctive therapy in the treatment of partial onset seizures in adults. The total daily dose should be divided into two or three times daily. Since pregabalin is eliminated primarily by renal system, the dose should be adjusted for patients with reduced renal function.

MANAGEMENT OF FIBROMYALGIA

Recommended dose of pregabalin for the treatment of fibromyalgia is 300 to 450mg/day. Dosing should start at 75mg two times a day (150mg/day) and may be increased to 150mg two times a day (300mg/day) within 1 week based on efficacy and tolerability.

PATIENTS WITH RENAL IMPAIRMENT

With reference to dose-dependent adverse reactions and as pregabalin is eliminated primarily by renal excretion, the dose should be adjusted in patients with reduced renal function. Dosage adjustment in patients with renal impairment should be based on creatinine clearance (Clcr).

USE IN PREGNANCY

Patients should be instructed to notify their physician if they become pregnant or intend to become pregnant during therapy, and to notify their physician if they are breast feeding or intend to breast feed during therapy.

DRUG INTERACTIONS

As pregabalin is excreted unchanged in the urine, undergoes negligible metabolism in humans (<2% of a dose recovered in urine as metabolites), and does not bind with plasma proteins, its pharmacokinetics are unlikely to be affected by other agents through metabolic interactions or protein binding displacement. In vitro and in vivo studies 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 would also not be expected to occur between pregabalin and commonly used antiepileptic drugs.

INSTRUCTIONS

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

PRESENTATION

GABIUN 50mg capsules:

GABIUN 50mg capsules are available in the Alu-Alu pack of 2x7's.

GABIUN 75mg capsules:

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GABIUN 100mg capsules:

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گیبائن کیپسول
(پریگیبلن)

ہدایات: دوا کو 30°C سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔



Manufactured by:
STANDPHARM PAKISTAN (PVT) LTD
20 km Ferozpur Road Lahore, Pakistan.