

PGLIN

Pregabalin

50 mg, 75 mg
100 mg, 150 mg
Capsule

پی جی لین کپسول
پریگیبالین

PGLIN (Pregabalin) is an anti convulsant and anxiolytic medication used to treat epilepsy, neuropathic pain, fibromyalgia, restless leg syndrome and generalized anxiety disorder. Its use in epilepsy is as an add-on therapy for partial seizures. When used before surgery, it reduces pain but results in greater sedation and visual disturbances. It is taken by mouth. The molecular weight of pregabalin is 159.23 gm. The molecular formula is $C_8H_{17}NO_2$

COMPOSITION:

Each capsule contains: Pregabalin..... 50mg, 75mg, 100mg, 150mg.

CLINICAL PHARMACOLOGY:

Pharmacokinetics

Absorption Pregabalin is absorbed from the intestines by an active transport process mediated via the large neutral amino acid transport.

Distribution pregabalin crosses the blood brain barrier and enters the system. The volume of distribution of an orally administered dose of pregabalin is approximately 0.56 L/kg.

Pregabalin is not significantly bound.

Metabolism

Pregabalin undergoes little or no metabolism

ELIMINATION:

Pregabalin is eliminated by the kidneys in the urine, mainly in its unchanged form. It has a relatively short elimination half-life, with a reported value of 6.3 hours.

Mechanism of Action

Pregabalin is a 3-isobutyl derivative of gamma-amino butyric acid (GABA) with anti convulsant, anti-epileptic, anxiolytic and analgesic activities. Although the exact mechanism of action is unknown, pregabalin selectively binds to alpha2delta (A2D) subunits of presynaptic voltage-dependent calcium channels (VDCCs) located in the central nervous system (CNS). Binding of pregabalin to VDCC A2D subunits prevents calcium influx and the subsequent calcium-dependent release of various neurotransmitters, including glutamate, norepinephrine, serotonin, dopamine and substance P, from the presynaptic nerve terminals of hyperexcited neurons; synaptic transmission is inhibited and neuronal excitability is diminished. Pregabalin does not bind directly to GABA-A or GABA-B receptors and does not alter GABA uptake or degradation.

INDICATIONS

PGLIN (Pregabalin) is indicated for the management of neuropathic pain associated with:

Diabetic peripheral neuropathy

Post herpetic neuralgia

Spinal cord injury

Fibromyalgia

PGLIN is also indicated adjunctive therapy for adult patients with partial onset seizures.

CONTRAINDICATIONS:

Pregabalin must not be used in patients hypersensitive to pregabalin or any other component of product.

PRECAUTIONS:

Hereditary problems of galactose metabolism: patients with rare hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Weight gain:** In the controlled studies, weight gain occurred more frequently in patients treated with pregabalin than in patients treated with placebo. Hypersensitivity. Reactions: there have been reports in the post-marketing experience of hypersensitivity reactions, including cases of angioedema dizziness and Somnolence pregabalin causes dizziness and somnolence. In the controlled studies, dizziness and somnolence generally began shortly after initiation of pregabalin and occurred more frequently at higher doses. Suicidal behavior and Ideation anti epileptic drugs (AED), including pregabalin, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior and / or any unusual changes in mood or behavior.

SIDE EFFECTS:

The most commonly reported adverse effects were dizziness and somnolence. Adverse effects were usually mild to moderate in intensity. Other adverse effects include fatigue, weight gain, dry mouth, headache, ataxia, oedema, diplopia, tremor, constipation, nausea, disturbance in attention, vertigo and peripheral swelling.

Psychiatric disorders:

Euphoric mood, libido decreased, irritability, disorientation and insomnia

Nervous system disorders:

Paraesthesia, amnesia, sedation **Gastrointestinal disorders:** Vomiting, flatulence and abdominal distension

Reproductive system and breast disorders:

Erectile dysfunction, General disorders and administration site disorders: Feeling drunk, feeling abnormal.

DRUG INTERACTIONS:

Since pregabalin is predominantly excreted unchanged in the urine, undergoes negligible metabolism in humans (<2% of a dose recovered in urine as metabolites), does not inhibit drug metabolism in vitro and is not bound to plasma proteins, pregabalin is unlikely to produce or be subjected to pharmacokinetic interactions.

DOSAGE**Neuropathic Pain Associated with Diabetic Peripheral Neuropathy**

The recommended starting dose for **PGLIN** is 150mg/day, given in two or three divided doses (75mg BID or 50mg TID), with or without food in patients with a creatinine clearance rate of at least 60ml/min. Efficacy of **PGLIN** has been demonstrated within the first week. Based on individual patient response and tolerability, the dose may be increased to 150mg BID (300mg/day) after one week pain associated with fibromyalgia. The recommended dosage is 300 to 450mg/day, given in two divided doses. The recommended starting dose for **PGLIN** is 150mg/day, given in two divided doses (75mg BID), with or without food in patients with a creatinine clearance rate of at least 60ml/min. Based on individual response and tolerability, the dose may be increased to 150mg BID (300mg/day) after one week patients who do not experience sufficient benefit with 300mg/day may be further increased to 225mg BID (450mg/day). In some patients, efficacy of **PGLIN** has been demonstrated within the first week for patients who experience significant and ongoing pain and can tolerate pregabalin 300mg/day well, maximum daily dose of 600mg (300mg twice a day, BID) can be used adjunctive therapy for adult patients with partial onset seizures or as directed by the physician.

STORAGE INSTRUCTIONS:

Keep out of the reach of children & store below 30°C.

Protect from sunlight & moisture

Improper storage may deteriorate the medicine

Do not use this medicine after the expiry date which is stated on the blister.

STABILITY:

See expiry on pack.

PRESENTATION:

PGLIN 50mg, 75mg, 100mg, 150mg capsule in pack of 14's.

Manufactured by :



PHARMA LORD

PHARMA LORD | 12km, Lahore
(PVT.) LIMITED | Road, Layyah.
Pakistan
www.pharma-lord.com

پی جی لین
پریگیبالن

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: بچوں کی پہنچ سے دور رکھیں۔

دوا کو دھوپ، گرمی اور نمی سے محفوظ رکھیں۔ ڈگری سینٹی گریڈ

سے کم درجہ حرارت پر رکھیں۔