

Gabalon

Pregabalin

COMPOSITION:

Gabalon Capsule: Each capsule contains pregabalin INN 50 mg.

PHARMACOLOGY:

Gabalon is a structural derivative of the inhibitory neurotransmitter gamma-amino butyric acid (GABA). It does not bind directly to GABA_A, GABA_B, or benzodiazepine receptor. It is inactive at serotonin and dopamine receptors and does not inhibit dopamine, serotonin, or noradrenaline reuptake. **Gabalon** binds with high affinity to the alpha-2-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system tissues. **Gabalon** oral bioavailability is $\geq 90\%$ and is independent of dose. It 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.

INDICATION:

Gabalon is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy and management of post herpetic neuralgia. It is also indicated for the adjunctive therapy for adult patients with partial onset seizures. It can be used for the management of fibromyalgia.

DOSAGE AND ADMINISTRATION:

Neuropathic pain associated with diabetic peripheral neuropathy: The maximum recommended dose of Pregabalin (**Gabalon**) is 100 mg three times a day (300 mg/day). Dosing should begin at 50 mg three times a day (150 mg/day) and may be increased to 300 mg/day within 1 week based on efficacy and tolerability.

Post-herpetic neuralgia: The recommended dose of Pregabalin (**Gabalon**) is 75 to 150 mg two times a day, or 50 to 100 mg three times a day (150 to 300 mg/day). Dosing should begin at 75 mg two times a day, or 50 mg three times a day (150 mg/day) and may be increased to 300 mg/day within 1 week based on efficacy and tolerability.

Adjunctive therapy for adult patients with partial onset seizures: Pregabalin (**Gabalon**) at doses of 150 to 600 mg/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 and given either two or three times daily.

Management of Fibromyalgia: The recommended dose of Pregabalin for fibromyalgia is 300 to 450 mg/day. Dosing should begin at 75 mg two times a day (150 mg/day) and may be increased to 150 mg two times a day (300 mg/day).

Neuropathic pain associated with spinal cord injury: The recommended dose range is 150 to 600 mg/day. The recommended starting dose is 75 mg two times a day (150 mg/day). The dose may be increased to 150 mg two times a day (300 mg/day) within 1 week based on efficacy and tolerability.

SIDE EFFECT:

The most common side effects include dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, and abnormal thinking.

CONTRAINDICATION:

Pregabalin (**Gabalon**) is contraindicated in patients with known hypersensitivity to Pregabalin or any of its components.

PRECAUTION:

Discontinuation of Pregabalin (**Gabalon**) without tapering may produce insomnia, nausea, headache and diarrhea. So it should be tapered gradually over a minimum of 1 week rather than discontinued abruptly. Creatinine kinase may be elevated if treated with Pregabalin. It should be discontinued rapidly if myopathy is diagnosed or suspected or if creatinine kinase is elevated markedly.

USE IN PREGNANCY AND LACTATION:

Pregnancy: Pregnancy category C. So it should only be used if potential benefit justifies the potential risks to the fetus.

Nursing mother: It is not known if pregabalin is excreted in human milk; it is, however, present in the milk of rats. So it should be used in nursing mother only if there is a clear benefit over the risk.

DRUG INTERACTION:

There are no significant interactions between Pregabalin and other antiepileptic drugs like carbamazepine, valproic acid, lamotrigine, phenytoin, phenobarbital and topiramate. Co-administration of Pregabalin with the oral contraceptives like norethisterone and ethinyl oestradiol does not influence the steady state pharmacokinetics of either agent. Pregabalin may potentiate the effects of ethanol and lorazepam.

PHARMACEUTICAL PRECAUTION:

It should be stored in a cool and dry place, protected from light and moisture. Should be stored at room temperature below 30°C.

HOW SUPPLIED:

Gabalon Capsule: Each box contains 3x10 capsules in blister pack.

Manufactured by:

 **MEDICON Pharmaceuticals Ltd.**
Mirpur, Dhaka, Bangladesh

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