Neurolin®

Pregabalin

COMPOSITION
Neurolin® 25 Capsule : Each capsule contains Pregabalin INN 25 mg.
Neurolin® 50 Capsule : Each capsule contains Pregabalin INN 50 mg.
Neurolin® 75 Capsule : Each capsule contains Pregabalin INN 75 mg.
Neurolin® 150 Capsule : Each capsule contains Pregabalin INN 150 mg.

PHARMACOLOGY
Neurolin® 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. **Neurolin®** binds with high affinity to the alpha-2-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system tissues. **Neurolin®** oral bioavailability is ≥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
Neurolin® 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 and neuropathic pain associated with spinal cord injury.

DOSAGE & ADMINISTRATION
Neuropathic pain associated with diabetic peripheral neuropathy: The maximum recommended dose of Pregabalin (**Neurolin®**) is 100 mg three times a day (300 mg/day) in patients with creatinine clearance of at least 60 mL/min. 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 (**Neurolin®**) is 75 to 150 mg two times a day, or 50 to 100 mg three times a day (150 to 300 mg/day) in patients with creatinine clearance of at least 60 mL/min. 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 (**Neurolin®**) 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. In general, it is recommended that patients be started on a total daily dose no greater than 150 mg/day (75 mg two times a day, or 50 mg three times a day). Based on individual patient response and tolerability, the dose may be increased to a maximum dose of 600 mg/day.
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) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient benefit with 300 mg/day may be further increased to 225 mg two times a day (450 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. Patients who do not experience sufficient pain relief after treatment with 300 mg/day and who tolerate pregabalin may be treated with up to 300 mg two times a day. **Neurolin®** capsules can be taken without regards to meals.

Pregabalin Dosage Adjustment Based on Renal Function:

Creatinine Clearance (mL/min)	Total Pregabalin Daily Dose (mg/day)*				Dose Regimen
60	150	300	450	600	BID or TID
30–60	75	150	225	300	BID or TID
15–30	25-50	75	100-150	150	QD or BID
<15	25	25-50	50-75	75	QD

TID= Three divided doses; BID = Two divided doses; QD = Single daily dose.
*Total daily dose (mg/day) should be divided as indicated by dose regimen to provide mg/dose.

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

PRECAUTIONS AND WARNING
Discontinuation of Pregabalin (**Neurolin®**) 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.

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

USE IN PREGNANCY AND LACTATION
Pregnancy: Pregnancy category C. So it should only 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.

PAEDIATRIC USE
The safety and efficacy of pregabalin in paediatric patients have not been established.

STORAGE
Store at a cool & dry place, protected from light and moisture. Keep out of reach of the children.

HOW SUPPLIED
Neurolin® 25 Capsule: Each box contains 30 capsules in blister packs.
Neurolin® 50 Capsule: Each box contains 30 capsules in blister packs.
Neurolin® 75 Capsule: Each box contains 30 capsules in blister packs.
Neurolin® 150 Capsule: Each box contains 10 capsules in blister packs.

Manufactured by :
SQUARE
PHARMACEUTICALS LTD.
PABNA, BANGLADESH

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