Description: Nervalin® is a preparation of Pregabalin INN. Nervalin® is a structural derivative of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA). It does not directly bind to $GABA_A$, $GABA_B$ or benzodiazepine receptors. Nervalin® does not block sodium channels, is not active at opiate receptors and does not alter cyclooxygenase enzyme activity. It is inactive at serotonin and dopamine receptors and does not inhibit dopamine, serotonin, or noradrenaline reuptake. It binds with high affinity to the $alpha_2$-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system tissues. It is well absorbed after oral administration. Following oral administration of Nervalin® capsules under fasting conditions, peak plasma concentrations occur within 1.5 hours. Oral bioavailability of Nervalin® is ≥90% and is independent of dose. The rate of Nervalin® absorption is decreased when given with food, resulting in a decrease in C_{max} of approximately 25% to 30% and an increase in T_{max} to approximately 3 hours. Administration of Nervalin® with food has no clinically relevant effect on the total absorption of Pregabalin. Therefore, Nervalin® can be taken with or without food. It does not bind to plasma proteins. Nervalin® is eliminated from the systemic circulation primarily by renal excretion as unchanged drug with a mean elimination half-life of 6.3 hours. **Indications:** Nervalin® is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia & spinal cord injury. It is also indicated as 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 Nervalin® is 100 mg 3 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 and may be increased to 300 mg/day within 1 week based on efficacy and tolerability. *Neuropathic pain associated with postherpetic neuralgia:* The recommended dose of Nervalin® 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). The dose may be increased to 300 mg/day within 1 week based on efficacy and tolerability. *Adjunctive therapy for adult patients with partial onset seizures:* The recommended dose of Nervalin® for adults is 150 to 600 mg/day by 2 or 3 divided doses as adjunctive therapy in the treatment of partial onset seizures. 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 is 300 to 450 mg/day. Dosing should begin at 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 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 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 2 to 3 weeks of treatment with 150 mg two times a day and who tolerate Nervalin® may be treated with up to 300 mg two times a day. Nervalin® can be taken with or without food. **Contraindications:** Nervalin® is contraindicated in patients with known hypersensitivity to Pregabalin or any of its components. **Precautions:** Abrupt or rapid discontinuation of Pregabalin may produce some symptoms including insomnia, nausea, headache and diarrhea. So Pregabalin should be tapered gradually over a minimum of 1 week rather than discontinued abruptly. Pregabalin treatment may associate with creatine kinase elevations. It should be discontinued if myopathy is diagnosed or suspected or if markedly elevated creatine kinase levels occur. **Side effects:** Pregabalin is well tolerated but a few side effects like dizziness, somnolence, dry mouth, edema, weight gain, abnormal thinking and blurred vision may occur. **Overdose:** Overdose of up to 8000 mg has been reported. Pregabalin can be removed by emesis or gastric lavage. **Use in pregnancy and lactation:** Pregnancy: Pregnancy category C. So Pregabalin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nursing mother: Pregabalin may be secreted through the breast milk like other drugs. So it should be used in nursing women only if the benefits clearly overweigh the risks. Pediatric use: The safety and efficacy of Pregabalin in pediatric patients have not been established. **Pharmaceutical precautions:** Store at a cool & dry place, protected from light and moisture. Keep out of reach of the children. **Packaging:** Nervalin® 50 capsule: Box containing 30 capsules in 3×10's blister strips. Each capsule contains Pregabalin INN 50 mg. Nervalin® 75 capsule: Box containing 30 capsules in 3×10's blister strips. Each capsule contains Pregabalin INN 75 mg.