

## ABRIDGED PRESCRIBING INFORMATION: PREGABID GEL

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**COMPOSITION:** Pregabalin Gel 8 %w/w. Dosage form: Topical Gel Strength: 8 % w/w (Each gram of Gel contains, Pregabalin IP80 mg.)

**INDICATIONS:** Pregabalin Gel 8% w/w is indicated for the treatment of Diabetic neuropathic pain.

**DOSAGE AND ADMINISTRATION:** To be applied as a thin film over effected area twice a day as directed by Physician.

**CONTRAINDICATIONS:** Known hypersensitivity to Pregabalin or any of its components of the Topical Pregabalin Gel.

**WARNINGS AND PRECAUTIONS:** The absorption of Pregabalin from Topical Pregabalin gel into the systemic circulation is expected to be minimal. Hence serum concentrations of Pregabalin after Topical application are expected to be very low as compared to oral Pregabalin. Hence, Pregabalin Gel is expected to be well tolerated.

**USE IN SPECIFIC POPULATIONS: Pregnancy:** The systemic absorption of Pregabalin from topical gel formulations is expected to be minimal, leading to very low serum concentrations compared to oral administration, which should result in reduced adverse effects. **DRUG INTERACTIONS:** The absorption of Pregabalin from the Pregabalin Topical Gel into the systemic circulation is expected to be minimal. Hence serum concentrations of Pregabalin after Topical application are expected to be very low as compared to oral Pregabalin. Hence drug interactions of Topical Pregabalin are expected to be low or minimal. **ADVERSE REACTIONS:** In the phase III Clinical trial of Topical Pregabalin, it was observed that Topical Pregabalin was well tolerated. In comparison with Topical Pregabalin patients treated with oral Pregabalin reported dizziness and somnolence. **OVERDOSE:** The absorption of Pregabalin from Topical gel formulation into the systemic circulation is expected to be minimal. Hence serum concentrations of Pregabalin after Topical application are expected to be very low as compared to oral Pregabalin.

**SHELF LIFE:** 24 month **STORAGE:** Store at a temperature not exceeding 30°C. Protect from light.

**FOR FURTHER INFORMATION, PLEASE REFER FULL PRESCRIBING INFORMATION. Revised as on 23<sup>rd</sup> October 2024.**