PREGABA GEL/ PREGALIN GEL

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **PREGABA GEL/ PREGALIN GEL** (Pregabalin Gel 8 % w/w)

[Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: The mechanism of action of Topical Pregabalin may involve an increase in the synthesis of Nitric Oxide and the release of endogenous opioids. It may be hypothesized that Pregabalin may increase the synthesis of nitric oxide, which in tum may increase the release of endogenous opioids to attenuate neuropathic pain.

INDICATIONS: 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.

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

WARNINGS & PRECAUTIONS:. The following precautions are mentioned for oral Pregabalin.

Angioedema (e.g. swelling of the throat, head and neck) can occur and may be associated with life-threatening respiratory compromise requiring emergency treatment. Discontinue Pregabalin immediately in these cases. Hypersensitivity reactions (e.g., hives, dyspnea, and wheezing) can occur. Discontinue Pregabalin immediately in these patients, Increased seizure frequency or other adverse reactions may occur if Oral Pregabalin is rapidly discontinued. Withdraw Pregabalin gradually over a minimum of 1week, Antiepileptic drugs, including Oral Pregabalin increase the risk of suicidal thoughts or behaviour, Oral Pregabalin may cause peripheral edema. Exercise caution when co-·administering Oral Pregabalin and thiazolidinedione antidiabetic agents, Oral Pregabalin may cause dizziness and somnolence and impair patients' ability to drive or operate machinery.

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 However, oral Pregabalin use has the following data available regarding drug interactions.

Since oral Pregabalin is predominantly excreted unchanged in the urine, undergoes negligible metabolism in humans (less than 2% of a dose recovered in urine as metabolites), and does not bind to plasma proteins, its pharmacokinetics are unlikely to be affected by other agents through metabolic interactions or protein binding displacement.

Pregabalin co-administration did not have any drug interactions with oxycodone, lorazepam, or ethanol. Although no pharmacokinetic interactions were seen, additive effects on cognitive and gross motor functioning were seen when Pregabalin was co-administered with these drugs.

ADVERSE REACTIONS: In the phase Ill 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.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/PREGABA GEL/PREGALIN GEL/Oct-24/01/ABPI
(Additional information is available on request)