

TOPLAP GEL

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

Abbreviated Prescribing information for **TOPLAP GEL** [Lidocaine and Prilocaine Gel]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION TOPLAP GEL when applied to intact skin under occlusive dressing, provides dermal analgesia by the release of Lidocaine and Prilocaine from the Gel into the epidermal and dermal layers of the skin, leading to accumulation of active ingredients in the vicinity of the dermal pain receptors and nerve endings. Both the active ingredients stabilize the neuronal membranes by inhibiting the ionic fluxes required for initiation and conduction of impulses, thereby resulting in local anaesthetic action..

INDICATIONS: It is indicated for the treatment of as a topical and aesthetic for use on normal intact skin for local anaesthesia.

DOSAGE AND ADMINISTRATION: TOPLAP Gel should not be used in infants under the age of one month nor in infants under the age of twelve months who are receiving treatment with methemoglobinemia inducing agent. 1 to 2gm for 10 cm² of TOPLAP Gel to be applied on the intact skin under occlusive dressing for 1 to 2 hrs. Inadequate application results in inadequate analgesia.

CONTRAINDICATION: TOPLAP Gel is contraindicated in patients with known history of sensitivity to Lidocaine, Prilocaine and any other component of the product. TOPLAP Gel should not be used in those rare patients with congenital or idiopathic Methemoglobinemia nor in infants under the age of twelve months who are receiving treatment with Methemoglobin inducing agent. Application of TOPLAP Gel is contraindicated in any clinical situation in which its migration into the middle ear is possible.

WARNINGS & PRECAUTIONS: The use of TOPLAP Gel in the areas close to the eyes should be exercised with caution. If eye contact occurs, immediately wash out the eyes with water or saline and protect the eye until sensation returns. Repeated doses may increase blood levels of Prilocaine and Lidocaine. TOPLAP Gel should be used with caution in patients who are more sensitive to the systemic effects of Prilocaine and Lidocaine including acutely ill, debilitated and elderly patients.

DRUG INTERACTIONS: TOPLAP Gel should be used with caution in patient receiving class I antiarrhythmic drugs (such as Tocainide & Mexiletine), since the toxic effect are additive and potentially synergistic.

ADVERSE REACTIONS: Urticarial, angioedema, bronchospasm, shock, erythema, edema, locus of abnormal sensation, hyperpigmentation, light headedness, nervousness, euphoria, dizziness, drowsiness, blurred of double vision, vomiting, sensation od heat or cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression, arrest, bradycardia, hypotension, cardiovascular collapse leading to arrest.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/TOPLAP GEL 10 gm and 30 gm/Aug-23/02/ABPI

(Additional information is available on request)