TOPICAINE ULTRA- topicaine ultra gel
Oncora Pharma, LLC

Topicaine Ultra

TOPICAINE™ Ultra 2% – Lidocaine HCl 2% Gel

Oncora Pharma

NDC 85477-307-85

Active Ingredient

Lidocaine HCl 2%

Purpose

Topical Analgesic

Uses

For the temporary relief of pain and itching associated with:

- minor burns
- sunburn
- minor cuts
- scrapes
- insect bites
- minor skin irritations

Warnings

For external use only.

When using this product:

- Avoid contact with the eyes.
- Do not use in large quantities, particularly over raw surfaces or blistered areas.

Stop use and ask a doctor if:

- Condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 2 years and older: Apply externally to the affected area up to 3–4 times daily.
- Children under 2 years: Do not use. Consult a doctor.

Other Information

Store at USP controlled room temperature 20° to 25°C (68° to 77°F).

Inactive Ingredients

Inactive ingredients are printed on the product container label.

Aqua (Water), Hydroxyethylcellulose, Phenoxyethanol, Ethylhexylglycerin, Sodium Hydroxide, Lactic Acid.

See bottle label below for full ingredient listing.

Manufactured for: Oncora Pharma, Dallas, TX 75228

Principal Display Panel

NDC: 85477-307-85
Topicaine
Ultra External Gel 2%
Lidocaine 2%
Net Wt. 3 oz. (85g)

TOPICAINE ULTRA

topicaine ultra gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:85477-307
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROXYETHYLCELLULOSE (UNII: T4V6TWG28D)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
LACTIC ACID (UNII: 33X04XA5AT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85477-307-85	85 g in 1 TUBE; Type 0: Not a Combination Product	03/01/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/01/2026	

Labeler - Oncora Pharma, LLC (119482542)

Revised: 3/2026 Oncora Pharma, LLC