TRILOGEL- lidocaine hydrochloride gel Trifluent Pharma LLC

Trilogel™

Drug Facts

Active Ingredient

Lidocaine HCl, USP 2.8%

Purpose

Topical analgesic

Uses

For the temporary relief of pain associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations.

Warnings

For external use only

Do not use in large quantities, particularly over raw surfaces or blistered areas.

When using this product avoid contact with eyes

Stop use and ask a physician if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician.

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Directions

- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
- Children under 2 years of age: Do not use; consult a physician.

Other Information

Store at 20-25°C (68-77°F). Protect from freezing.

Inactive Ingredients

Caprylyl Glycol, Carica Papaya (Papaya) Fruit Extract, Disodium EDTA, Ethylhexylglycerin, Glycerin, Hexylene Glycol, Hydroxypropylcellulose, Phenoxyethanol, Purified Water, Sodium Lactate, Xanthan Gum.

Questions or Comments?

(210) 944-6920

PRINCIPAL DISPLAY PANEL - 57 G Pouch Label

Tear at notch to open. Do not use if seal is broken.

NDC: 73352-620-01

TRIFLUENT PHARMA™

Trilogel™

Lidocaine HCl 2.8%

Topical Analgesic Gel

For the temporary relief of pain associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations.

NET WT. 2 OZ. (57 G)

NDC: 73352-620-01



Trilogel™

Lidocaine HCI 2.8%

Topical Analgesic Gel

For the temporary relief of pain associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations.

NET WT. 2 OZ. (57 G)

Drug Facts

Active IngredientPurpose

Lidocaine HCI, USP 2.8%.....Topical analgesic

Drug Facts (continued)

inactive ingredients

Caprylyl Glycol, Carica Papaya (Papaya) Fruit Extract, Disodium EDTA, Ethylhexylglycerin, Glycerin, Hexylene

Uses

For the temporary relief of pain associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations

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- Children under 2 years of age: Do not use; consult a physician.

Other Information

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Glycol, Hydroxypropylcellulose, Phenoxyethanol, Purified Water, Sodium Lactate, Xanthan Gum.

Questions/Comments?

(210) 944-6920

MANUFACTURED FOR:

Trifluent Pharma, LLC San Antonio, TX 78213

MANUFACTURED IN THE U.S.A.

620-01 REV01 05/2024



TRILOGEL

lidocaine hydrochloride gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73352-620

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	28 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
XANTHAN GUM (UNII: TTV12P4NEE)			
GLYCERIN (UNII: PDC6A3C0OX)			
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)			
PAPAYA (UNII: KU94FIY6JB)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
HEXYLENE GLYCOL (UNII: KEH0A3F75J)			
SODIUM LACTATE (UNII: TU7HW0W0QT)			

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:73352-620- 01	1 in 1 POUCH	06/24/2024				
1		57 g in 1 TUBE; Type 0: Not a Combination Product					

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH DRUG	M017	06/24/2024		

Labeler - Trifluent Pharma LLC (117167281)

Revised: 6/2024 Trifluent Pharma LLC