PAIN RELIEVING CREAM LIDOCAINE- benzyl alcohol, lidocaine hci cream Trifecta Pharmaceuticals USA LLC

Globe Pain Relieving Cream+ Lidocaine

Active Ingredient

Lidocaine HCL 4%

Purpose

Topical Anasthetic

Benzyl Alcohol 10%

Purpose

Topical Anesthetic

Uses

Temporary Pain Relief

Do Not Use

- On wounds or damaged skin
- In large quantities
- With a heating pad
- if you are allergic to any ingredients of this product

When Using this Product

- Use only as direcgted
- Avoid contact with eyes, mucous membranes or rashes
- Do not bandage tightly

Warnings

For external Use Only

Do not use

- in eyes
- in large quantities
- over raw or blistered areas, or on deep puncture wounds, animal bites, or serious burns
- for more than one week unless directed by a doctor

If Pregnant or Breast Feeding

Ask a health professional before use

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (800-222-1222) right away

Directions

Adults and children over 12 years

- clean and dry affected area
- Apply to affected area not more than 3 to 4 times daily

Children 12 years or younger

ask a doctor

Stop Use and Ask a Doctor If

- Skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering
- Conditions worsen
- Symptoms persist for more than 7 days
- Symptoms clear up and occur again within a few days

Other Information

- Avoid storing product in direct sunlight
- Protect product from excessive moisture
- Store with lid closed tightly

Inactive Ingredients

Aloe barbadensis leaf juice, aminomethyl propanol, Butylene glycol, carbome interpolymer type A (allyl sucrose crosslinked), Ceteth-10 phosphate, Cetostearyl alcohol, Dihexadecyl phosphate, Dimethicone, Glyceryl 1-stearate, Hydroxyethly acrylate/sodium acryloydimethyl taurate copolymer, maltodextrin, polysorbate 80, SD alcohol, Steareth-21, water

Distributed By

Trifecta Pharmaceuticals USA®

101 NE Third Avenue, Suite 1500

Ft. Lauderdale, FL. 33301 USA

www.trifecta-pharma.com

Questions

Call 1-888-296-9067

OUTSIDE BOX



INNER TUBE





NET WT. 3 oz. (85g)

PAIN RELIEVING CREAM LIDOCAINE

benzyl alcohol, lidocaine hci cream

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:69396-139

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g		
BENZYL ALCOHOL (UNII: LKG8494WBH) (BENZYL ALCOHOL - UNII:LKG8494WBH)	BENZYL ALCOHOL	10 g in 100 g		

Inactive Ingredients				
Ingredient Name	Strength			
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)				
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)				
WATER (UNII: 059QF0KO0R)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)				
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)				
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)				
STEARETH-21 (UNII: 53J3F32P58)				
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)				
POLYSORBATE 80 (UNII: 60ZP39ZG8H)				
ALCOHOL (UNII: 3K9958V90M)				

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-139- 03	1 in 1 BOX	08/23/2023	
1		85 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	08/23/2022			

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)

Revised: 11/2023 Trifecta Pharmaceuticals USA LLC