

LIDOCAINE PAIN RELIEVING CREME- lidocaine hydrochloride cream
Velocity Pharma LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Lidocaine Pain Relieving Creme- CareOne

Lidocaine Pain Relieving Creme

Drug Facts

Active ingredient

Lidocaine HCl 4%

Purpose

Topical anesthetic

Uses

temporarily relieves minor pain

Warnings

For external use only

Do not use

- on large areas of the body or on cut, irritated or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor

When using this product

- use only as directed. Read and follow all directions and warnings on this carton.
- do not allow contact with the eyes
- do not bandage or apply local heat (such as heating pads) to the area of use

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children and pets.

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

Directions

adults and children over 12 years:

- apply a thin layer to affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period. After applying wash hands with soap and water.

children 12 years and younger: ask a doctor

Inactive ingredients

butylated hydroxy toluene, cetomacrogol 1000, cetostearyl alcohol, cetyl alcohol, disodium EDTA, disodium hydrogen phosphate anhydrous, light liquid paraffin, propylene glycol, purified water, sorbic acid, transcitol P, white petroleum jelly.

Keep Carton As It Contains Important Information

Close cap tightly between uses.

PRINCIPAL DISPLAY PANEL

The diagram shows the principal display panel for CAREone Maximum Strength PAIN RELIEVING CREAM 4% Lidocaine. The packaging is blue and yellow. The front panel features the CAREone logo at the top, followed by three bullet points: FAST ACTING, TARGETS PAIN, PENETRATES AGGRAVATED NERVES, NO IRRITATION, NO BURNING, NON-GREASY. Below these are four circular icons representing areas of application: Hand & Wrist, Foot, Ankle & Leg, Knee & Elbow, and Back, Neck & Shoulder. The product name 'PAIN RELIEVING CREAM 4% Lidocaine' is prominently displayed in a yellow and red banner. Below the banner, it states 'Compare to the Active Ingredient in Aspercreme® with 4% Lidocaine*'. Further down, it lists 'FAST ACTING', 'TARGETS PAIN', 'PENETRATES AGGRAVATED NERVES', 'NO IRRITATION', 'NO BURNING', 'NON-GREASY', and 'NET WT 4.7 oz (133 g)'. A 'DISTRIBUTED BY:' section lists FOODHOLD, U.S.A., LLC, LANDOVER, MD 20785, 1-877-846-9949, © 2017 S&S Brands, LLC, and 'Quality guaranteed or your money back.' The back panel features the CAREone logo, 'MAXIMUM STRENGTH 4% LIDOCAINE AVAILABLE OVER - THE - COUNTER', and a 'Drug Facts' section. Dimensions are provided on the left and right sides: 37.99, 35.46, 66.57, 35.99, 103.25, and 279.25 mm.

LIDOCAINE PAIN RELIEVING CREME

lidocaine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 168-206
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

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PARAFFIN (UNII: I9O0E3H2ZE)	
CETETH-20 (UNII: I835H2IHHX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBIC ACID (UNII: X045WJ989B)	
PETROLATUM (UNII: 4T6H12BN9U)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76 168-206-33	1 in 1 CARTON	09/30/2020	
1		133 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 not final	part348	09/30/2020	

Labeler - Velocity Pharma LLC (962198409)