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

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Drug Facts

Active ingredient

Lidocaine HCI 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

children 12 years and younger: ask a doctor

Inactive ingredients

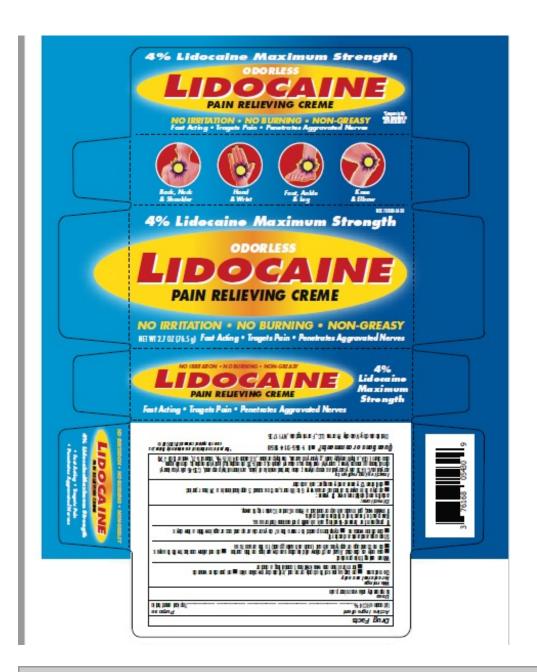
Butylated hydroxyl toluene,cetostearyl alcohol,cetomacrogol 1000,cetyl alcohol,disodium EDTA,disodium hydrogen phosphate,light liquid paraffin,propylene glycol,sorbic acid,transquitol P, white petroleum jelly

Keep Carton As It Contains Important Information

Close cap tightly between uses.

PRINCIPAL DISPLAY PANEL

ODOR FREE WITH 4% LIDOCAINE MAXIMUM STRENGTH Pain Relieving Crème Net wt 2.7 oz (76.5 g)



LIDOCAINE PAIN RELIEVING CREME

lidocaine hydrochloride cream

Product Information

1 Todact Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76168-054

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength

BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-2 (UNII: 7H8 VAM7778)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
SODIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO 53M6 F)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBIC ACID (UNII: X045WJ989B)	
PETROLATUM (UNII: 4T6H12BN9U)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76168-054-30	1 in 1 CARTON	03/03/2017	
1		76.5 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	03/03/2017	

Labeler - Velocity Pharma LLC (962198409)

Revised: 3/2017 Velocity Pharma LLC