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 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
Care one

LIDOCAINE PAIN RELIEVING CREME

lidocaine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76168-201
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**
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PARAFFIN (UNII: I9O0E3H2ZE)	
CETETH-2 (UNII: 7H8VAM7778)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBIC ACID (UNII: X045WJ989B)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76168-201-32	1 in 1 CARTON	09/14/2017	
1		130 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	09/14/2017	

Labeler - Velocity Pharma LLC (962198409)

Registrant - Velocity Pharma LLC (962198409)

Establishment

Name	Address	ID/FEI	Business Operations

Yash Pharmaceuticals		871409551	manufacture(76168-201)