LIDOCAINE PAIN RELIEVING CREME- lidocaine hydrochloride cream Yash Pharmaceuticals

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.

Outer Label

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

192 bottles in a case.

Active Ingredic	e nt 4%		Topical Anesthetic
BATCH NO.	LDC703	QUANTITY	$1 \times 16 \times 6 \times 133 \text{ g} = 96 \text{ Bottles}$
MFG.DATE	09/2017	SHIPPER NO.	01 out of 30
	00/00/0	GROSS WT.	kg.
EXP. DATE	08/2019	NET WT.	kg.
REACH OF CH	KEEP OUT OF HILDREN AND PETS. AL USE ONLY.	STORE AT CON 59°F to 86° F (15°	TROLLED TEMPERATURE OF C to 30°C)
CONFORMANCE WITH THE F.D & C ACT AND REGULATIONS THEREUNDER		PROTECT FROM DIRECT SUNLIGHT/MOISTURE/FREEZING	
KHASRA NO. PARGANA: BI	MACEUTICALS 19-M, VILLAGE :RAIPUR HAGWANPUR,DIST: HAI TARAKHAND,INDIA 247 ps/39/UA/2016	RIDWAR	
Manufacturer 71301-006-24 NDC No.			
SHIPPED TO: VELOCITY PH 226/B SHERW FARMINGDAL	HARMA LLC OOD AVE,		
	76168-201-32		
Barcode No.		520	00352 3

LIDOCAINE PAIN RELIEVING CREME

lidocaine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71301-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDOCAINE - 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: 7FLD9 1C86K)	
SO DIUM PHO SPHATE, MO NO BASIC, ANHYDRO US (UNII: KH7I0 4HPUU)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBIC ACID (UNII: X045WJ989B)	
PETRO LATUM (UNII: 4T6H12BN9U)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:71301-006-24	192 in 1 CASE	03/17/2017	
1	76.5 g in 1 BOTTLE; 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 - Yash Pharmaceuticals (871409551)

Registrant - VELOCITY PHARMA (962198409)

Establishment			
Name	Address	ID/FEI	Business Operations
Yash Pharmaceuticals		871409551	manufacture(71301-006), label(71301-006)

Revised: 9/2017 Yash Pharmaceuticals