

## **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.*

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### **Lidocaine Pain Relieving Creme**

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#### ***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

**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.

Laser, Inkjet & Copier Label ST-1 A4      199.6mm x 287.1mm x 1      **Oddy**

<b>ODORLESS PAIN RELIEVING CREAM 4% LIDOCAINE</b>			
<b>Active Ingredient</b> Lidocaine HCl 4%.....		.....Topical Anesthetic	
BATCH NO.	LDC701	QUANTITY	1 x 8 x 24 x 76.5 g = 192 Bottles
MFG. DATE	03/2017	SHIPPER NO.	-- out of --
EXP. DATE	02/2019	GROSS WT.	
		NET WT.	
<b>WARNING:</b> KEEP OUT OF REACH OF CHILDREN AND PETS. FOR EXTERNAL USE ONLY.		STORE AT CONTROLLED TEMPERATURE OF 59°F to 86° F (15 to 30 °C )	
CONFORMANCE WITH THE F.D & C ACT AND REGULATIONS THEREUNDER		PROTECT FROM DIRECT SUNLIGHT/MOISTURE/FREEZING	
<b>MANUFACTURED BY:</b> YASH PHARMACEUTICALS KHASRA NO. 19-M, VILLAGE :RAIPUR PARGANA: BHAGWANPUR, DIST: HARIDWAR ROORKEE, UTTARAKHAND, INDIA 247667			
MFG. LIC. NO.	39/UA/2016		
LABELLER CODE	71301		
NDC No	71301-002-24		
<b>SHIPPED TO:</b> VELOCITY PHARMA LLC 226/B SHERWOOD AVE, FARMINGDALE, NY-11735			
NDC No	76168-054-30		
Barcode No			

Barcode No.



# LIDOCAINE PAIN RELIEVING CREME

lidocaine hydrochloride cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:7130 1-002
<b>Route of Administration</b>	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)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-2 (UNII: 7H8VAM7778)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
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:71301-002-24	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)

Revised: 3/2017

Yash Pharmaceuticals