

HOT AND COLD WITH LIDOCAINE PAIN RELIEVING- lidocaine hcl and menthol 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.

Hot and Cold Cream with Lidocaine

Drug Facts

HOT AND COLD CREAM with LIDOCAINE

PAIN RELIEVING CREAM

Drug Facts

Active Ingredients

Lidocaine HCl 4%

Menthol 1%

Purposes

Lidocaine- Topical anesthetic,

Menthol- Topical Analgesic

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 label
- rare cases of serious burns have been reported with products of this type
- do not bandage tightly or apply local heat (such as heating pads) to the area of use or use with a medicated patch
- avoid contact with eyes and mucous membranes
- a transient burning sensation may occur upon application but generally disappears in several days

Stop use and ask a doctor if

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days

- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

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 or 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

Cold'nHot with Lidocaine plus Menthol

Active Ingredient

Lidocaine HCl 4%..... Topical Anesthetic

Menthol 1%..... Topical Analgesic

BATCH NO.		QUANTITY	1x2x6x2x4 49.6 g = 96 Bottles
MFG.DATE		SHIPPER NO.	-- out of --
EXP. DATE		GROSS WT.	----- kg.
		NET WT.	----- kg.

WARNING: KEEP OUT OF REACH OF CHILDREN AND PETS. FOR EXTERNAL USE ONLY.

STORE AT CONTROLLED TEMPERATURE OF 59°F to 86° F (15°C to 30°C)

CONFORMANCE WITH THE F.D & C ACT AND REGULATIONS THEREUNDER

PROTECT FROM DIRECT SUNLIGHT/MOISTURE/FREEZING

MANUFACTURED BY:

YASH PHARMACEUTICALS
 KHASRA NO. 19-M, VILLAGE :RAIPUR
 PARGANA: BHAGWANPUR,DIST: HARIDWAR
 ROORKEE,UTTARAKHAND,INDIA 247667

Lic#UK/Drugs/39/UA/2016

Manufacturer Label 71301

Code No.

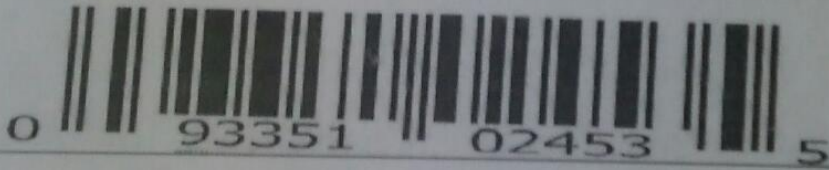
SHIPPED TO:

VELOCITY PHARMA LLC
 226B, SHERWOOD AVE,
 FARMINGDALE , NY-11735

NDC No 76168-400-31

Barcode No.



HOTCOLD (Lidocaine with Menthol Non Greasy Pain Relieving Cream)			
Active Ingredient			
Lidocaine HCl 4%.....		Topical Anesthetic	
Menthol 1%.....		Topical Analgesic	
BATCH NO.	LDM701	QUANTITY	8 x 24 x 1 x 76.5 gm = 192 Bottles
MFG.DATE	03/2017	SHIPPER NO.	1 out of 13
EXP. DATE	02/2019	GROSS WT.	
		NET WT.	
WARNING: 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	
MANUFACTURED BY:			
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		
SHIPPED TO:			
VELOCITY PHARMA LLC			
226/B SHERWOOD AVE,			
FARMINGDALE , NY-11735			
NDC No	76168-100-30		
Barcode No.			

HOT AND COLD WITH LIDOCAINE PAIN RELIEVING

lidocaine hcl and menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71301-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.4 g in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.1 g in 1 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)	
CETETH-20 PHOSPHATE (UNII: 921FTA1500)	
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:71301-001-24	192 in 1 CASE	03/02/2017	
1		76.5 g in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:71301-001-12	96 in 1 CASE	03/02/2017	
2		49.6 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	03/02/2017	

Labeler - Yash Pharmaceuticals (871409551)

Revised: 1/2018

Yash Pharmaceuticals