

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

Hot and Cold Pain Relieving Cream with Lidocaine- RA

Drug Facts

***HOT AND COLD CREAM with LIDOCAINE- RA
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.

PRINCIPAL DISPLAY PANEL

Hot and cold Cream -RA

Lidocaine

Plus Menthol

Pain Relieving Cream

Net Wt 2.7 OZ (76.5 g)



HOT AND COLD CREAM WITH LIDOCAINE- RA PAIN RELIEVING

lidocaine hcl and menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 168-301
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)	
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:76168-301-30	1 in 1 CARTON	05/25/2017	
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	05/25/2017	

Labeler - Velocity Pharma LLC (962198409)

Registrant - Velocity Pharma LLC (962198409)

Establishment

Name	Address	ID/FEI	Business Operations
Yash Pharmaceuticals		871409551	manufacture(76168-301)

Revised: 5/2017

Velocity Pharma LLC