

ICY HOT WITH LIDOCAINE NO-MESS- menthol and lidocaine liquid
Rite Aid Hdgrts Corp

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.

Icy Hot with Lidocaine No-Mess Applicator

ICY HOT with LIDOCAINE NO MESS

Drug Facts

Active ingredients

Lidocaine HCL

Menthol

Purposes

Lidocaine HCl

4%.....Topical
anesthetic

Menthol

1%.....Topical
analgesic

Use

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.
- avoid contact with eyes and mucous membranes
- rare cases of serious burns have been reported with products of this type
- do not apply to wounds or damaged, broken or irritated skin

- do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use
- a transient burning sensation may occur upon application but generally disappears in several days
- avoid applying into skin folds

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.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children over 12 years:

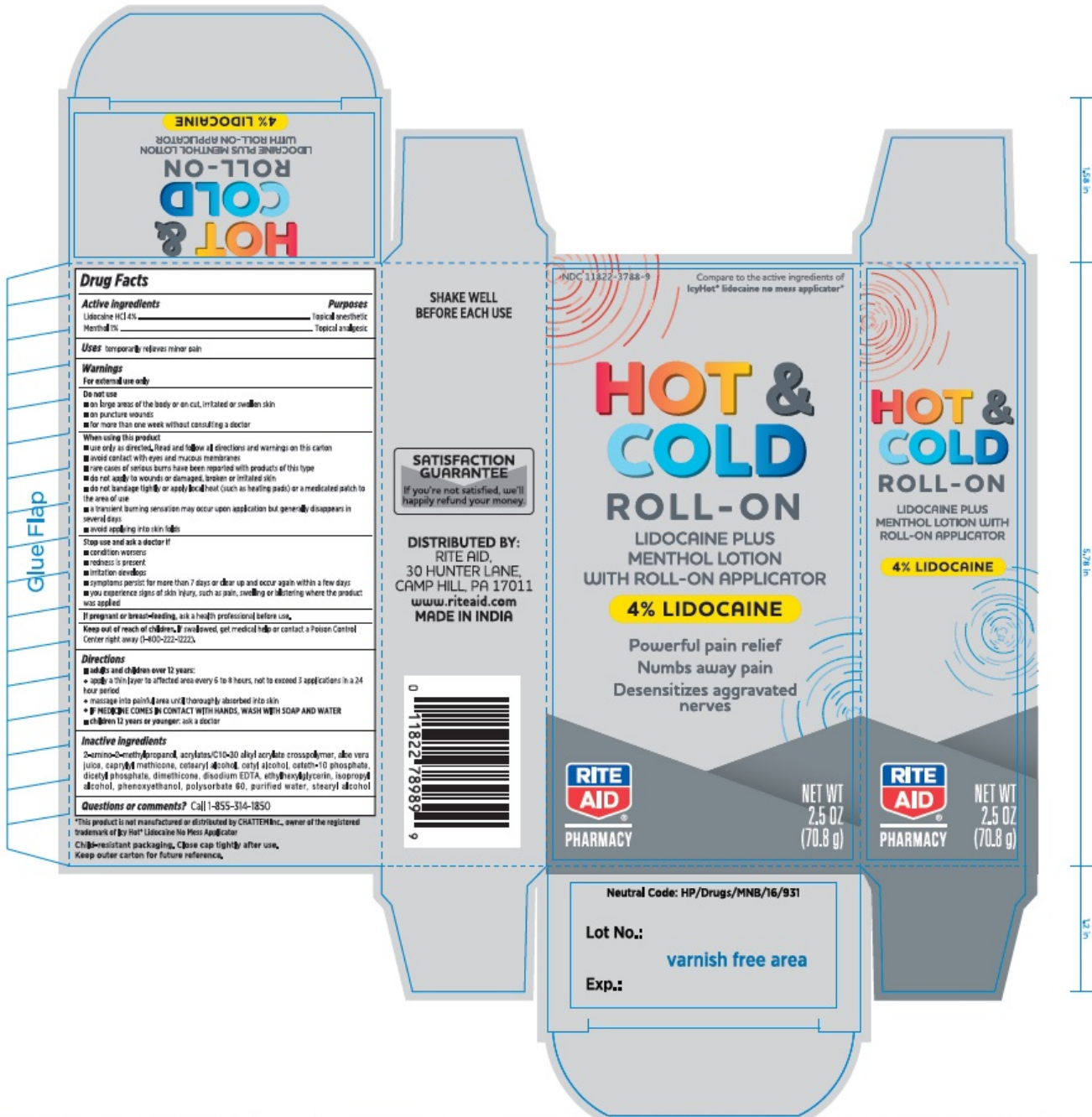
- apply a thin layer to affected area not more than 3 to 4 times daily
- massage into painful area until thoroughly absorbed into skin
- **IF MEDICINE COMES IN CONTACT WITH HANDS, WASH WITH SOAP AND WATER**

children 12 years or younger: ask a doctor

Inactive ingredients

2-amino-2methylpropanol, acrylates/C10-30 alkyl acrylate crosspolymer, aloe vera juice, caprylyl methicone, cetearyl alcohol, cetyl alcohol, ceteth-10 phosphate, dicetyl phosphate, dimethicone, disodium EDTA, ethylhexylglycerin, isopropyl alcohol, phenoxyethanol, polysorbate 60, purified water, stearyl alcohol

PRINCIPAL DISPLAY PANEL



ICY HOT WITH LIDOCAINE NO-MESS

menthol and lidocaine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-3788
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5VWN99N)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-3788-9	70.8 g in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/30/2020	

Labeler - Rite Aid Hdgrts Corp (014578892)

Registrant - Velocity Pharma LLC (962198409)

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Rite Aid Hdgrts Corp