# COOL N HEAT LIDOCAINE DRY- lidocaine and menthol, unspecified form spray TOPCO ASSOCIATES 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.

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#### Cool N' Heat Lidocaine Dry Spray

#### **Drug Facts**

Active ingredients	Purposes	
Lidocaine 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 label
- do not allow contact with the 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
- avoid spraying on face
- avoid inhalation of spray
- do not bandage or apply local heat (such as heating pads) or a medicated patch to area of use
- do not use at the same time as other topical analgesics
- 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

#### **Extremely Flammable**

- do not use near heat or flame or while smoking
- avoid long term storage above 104°F (40°C)
- do not puncture or incinerate. Contents under pressure
- do not store at temperatures above 120°F (49°C)

**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:

- spray affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period
- product will dry quickly on its own, and does not need to be rubbed in

children 12 years or younger: ask a doctor

#### **Inactive ingredients**

caprylic/capric triglyceride, isobutane, propylene glycol, SD alcohol 40B (30 %)

#### Questions or comments?

1-888-577-8033

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007

#### PRINCIPAL DISPLAY PANEL - 113 g Can Label

NDC 36800-908-35

TopCare health<sub>®</sub>

COMPARE TO ICY HOT® LIDOCAINE PLUS MENTHOL DRY SPRAY ACTIVE INGREDIENTS\*

MAXIMUM STRENGTH

Cool n' Heat Dry Spray Pain Relief with Lidocaine + Menthol

## LIDOCAINE 4% / TOPICAL ANESTHETIC MENTHOL 1% / TOPICAL ANALGESIC

•OUR PHARMACISTS• RECOMMEND

#### **CONTINUOUS SPRAY**

- Temporarily Numbs Pain Away
- Dries Instantly
- Non-Greasy

✓ QUALITY GUARANTEED

NET WT 4 OZ (113 g)

Scan here for more information or call 1-888-423-0139



lidocaine and menthol, unspecified form spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-850
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
ISOBUTANE (UNII: BXR49TP611)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:36800-850- 04	113 g in 1 CAN; Type 0: Not a Combination Product	05/01/2021	

Marketing Information			
Marketing Category		Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	05/01/2021	
FINAL			

### Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 3/2021 TOPCO ASSOCIATES LLC