

**THERAPEUTIC ICY COLD COOLING PAIN RELIEF- menthol spray**  
**APEX-CAREX HEALTHCARE PRODUCTS**

*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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**ACTIVE INGREDIENT**

NATURAL MENTHOL 6%

**PURPOSE**

COOLING PAIN RELIEF

**USES**

TEMPORARY RELIEF OF

- ARTHRITIS
- BACKACHE
- STRAINS
- SPRAINS

**WARNINGS**

FOR EXTERNAL USE ONLY.

DO NOT USE NEAR EYES, MOUTH, MUCUS MEMBRANES, CUTS, RASHES AND SORES. IF CONTACT OCCURS, FLUSH WITH COLD WATER.

DO NOT USE WITH HEATING PAD OR DEVICE, OR UNDER BANDAGES.

DO NOT USE IF PREGNANT OR BREASTFEEDING. PLEASE CONSULT YOUR PHYSICIAN PRIOR TO USE.

DO NOT APPLY TO WOUNDS OR DAMAGED SKIN.

STOP USE AND ASK A DOCTOR IF IRRITATION PERSISTS.

KEEP OUT OF REACH OF CHILDREN.

IF ACCIDENTALLY INGESTED, SEEK MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

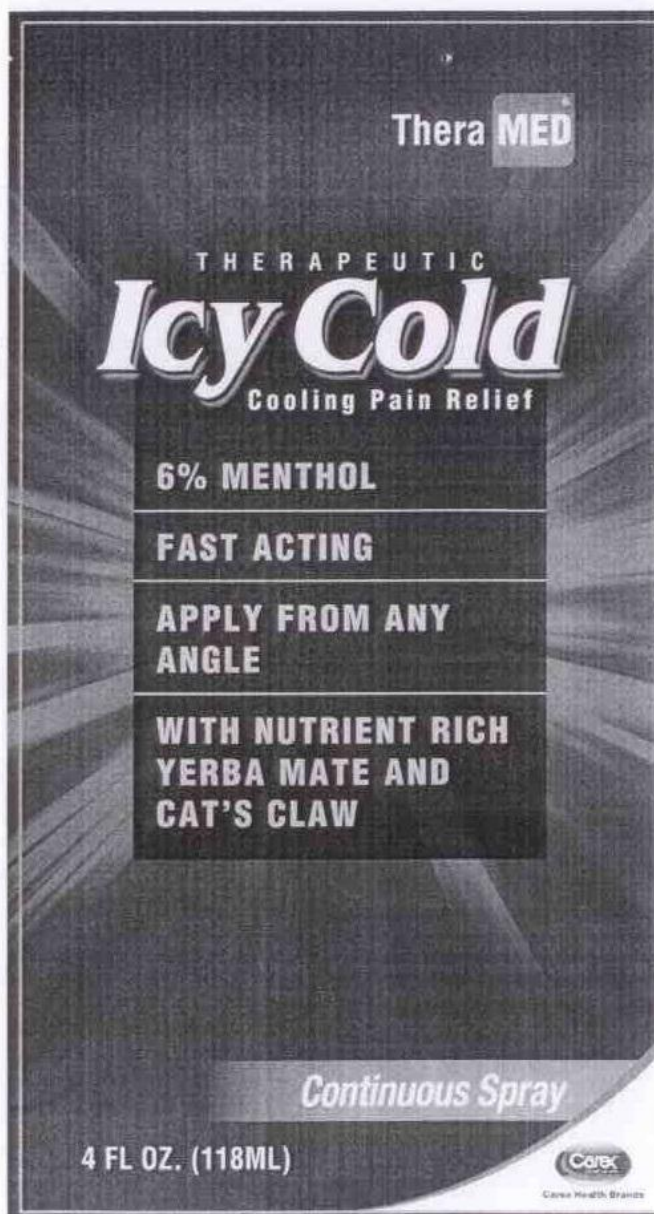
**DIRECTIONS**

- SHAKE GENTLY
- ADULTS AND CHILDREN 2 YEARS OF AGE AND OLDER, SPRAY ONTO AFFECTED AREA NOT MORE THAN 3 TO 4 TIMES DAILY.
- RUB IN THOROUGHLY UNTIL GEL IS ABSORBED.

**INACTIVE INGREDIENTS**

WATER, SD ALCOHOL, PROPYLENE GLYCOL, GLYCERINE, CARBOMER, ILEX PARAGUARIENSIS LEAF EXTRACT (YERBA MATE), HYDRATED SILICA, AMINOMETHYL PROPANOL, METHYL PARABEN, UNCARIA TOMENTOSA EXTRACT (CAT'S CLAW),

BOSWELIA SERRATA EXTRACT, CAMPHOR FOR SCENT



Drug Facts	
Active Ingredient	Purpose
Natural Menthol 6%.....	Cooling Pain Relief
Uses temporary relief of	
■ Arthritis ■ Backache ■ Strains ■ Sprains	
Warnings For external use only	
Do not use near eyes, mouth, mucus membranes, cuts, rashes and sores. If contact occurs, flush with cold water. Do not use with heating pad or device, or under bandages. Do not use if pregnant or breastfeeding. Please consult your physician prior to use. Do not apply to wounds or damaged skin.	
Stop use and ask a doctor if irritation persists.	
Keep out of reach of children. If accidentally ingested, seek medical help or contact a Poison Control Center immediately.	
Directions ■ shake gently ■ adults and children 2 years of age and older: spray onto affected area not more than 3 to 4 times daily. ■ rub in thoroughly until gel is absorbed.	
Inactive Ingredients Water, SD Alcohol, Propylene Glycol, Glycerine, Carbomer, Ilex Paraguariensis Leaf Extract (Yerba Mate), Hydrated Silica, Aminomethyl Propanol, Methyl Paraben, Uncaria Tomentosa Extract (Cat's Claw), Boswelia Serrata Extract, Camphor for scent.	



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NDC# XXXXX-XXX-XX



**THERAPEUTIC ICY COLD COOLING PAIN RELIEF**

menthol spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69851-102
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
METHYL PARABEN (UNII: A218C7H9T)	
UNCARIA TOMENTOSA LEAF (UNII: 487U8M3D2P)	
BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K)	
CAMPHOR OIL (UNII: 75IZZ8Y727)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69851-102-24	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/15/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/15/2015	

**Labeler** - APEX-CAREX HEALTHCARE PRODUCTS (622368947)

Revised: 11/2019

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