

**THERAPEUTIC ICY COLD COOLING PAIN RELIEF- menthol gel**  
**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.*

-----

**ACTIVE INGREDIENT**

NATURAL MENTHOL 3.9%

**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.

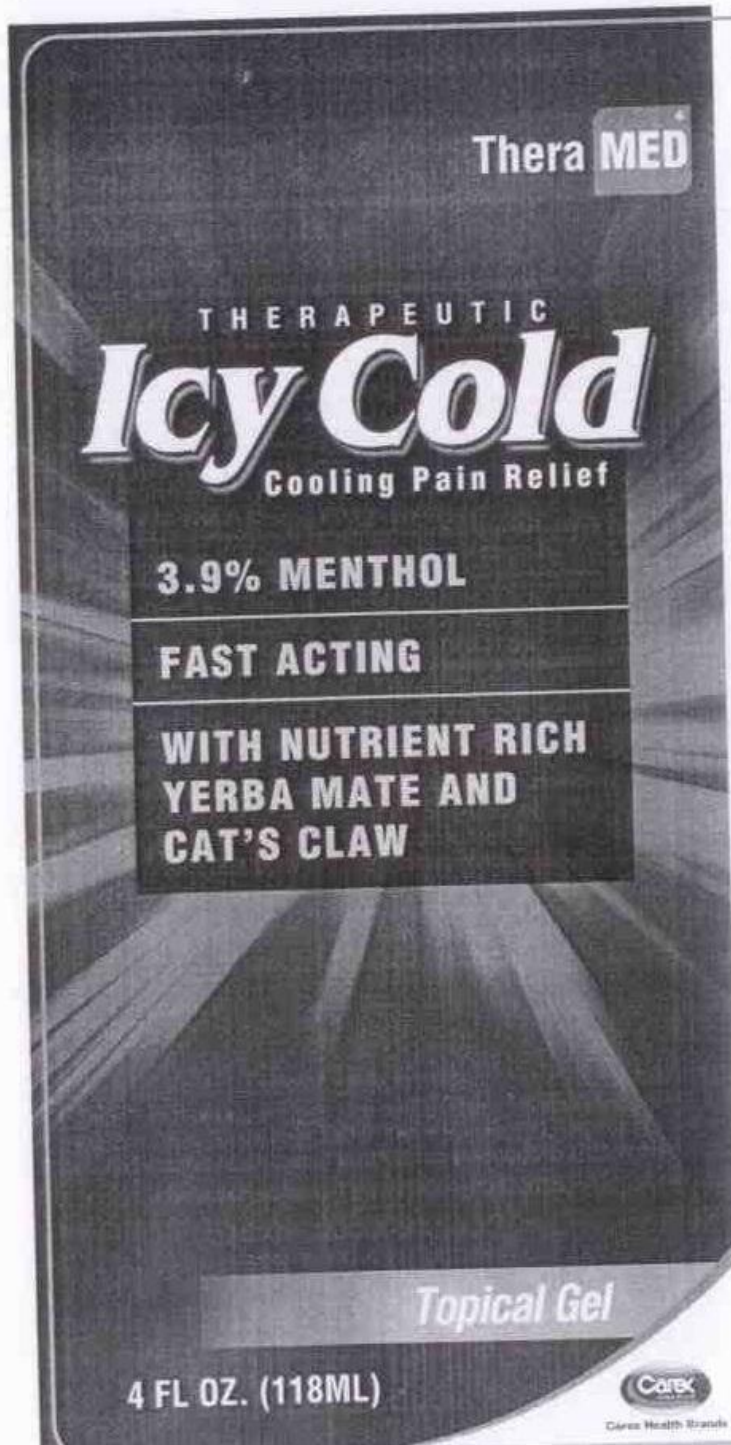
IF ACCIDENTALLY INGESTED, SEEK MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

**DIRECTIONS**

- ADULTS AND CHILDREN 2 YEARS OF AGE AND OLDER, APPLY TO 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 3.9%.....	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 ■ adults and children 2 years of age and older: apply to 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), Boswellia Serrata Extract, Camphor for scent



**Carex Health Brands**

Thera-Med® is a registered trademark of Carex Health Brands  
 PO Box 2526 Sioux Falls, SD 57101 • Phone 800.526.8051  
 A division of Compass Health Brands • Made in USA  
 www.carex.com 40-TMF6004\_00 ©2015

NDC# XXXXX-XXX-XX



**THERAPEUTIC ICY COLD COOLING PAIN RELIEF**

menthol gel

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69851-103
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	3.9 g in 100 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
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)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
UNCARIA TOMENTOSA LEAF (UNII: 487U8M3D2P)				
BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K)				
CAMPHOR OIL (UNII: 75IZZ8Y727)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69851-103-34	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2015	
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final		part348	05/15/2015	

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

Revised: 11/2019

APEX-CAREX HEALTHCARE PRODUCTS