

THERAPEUTIC ICY COLD COOLING PAIN RELIEF ROLL-ON- 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.

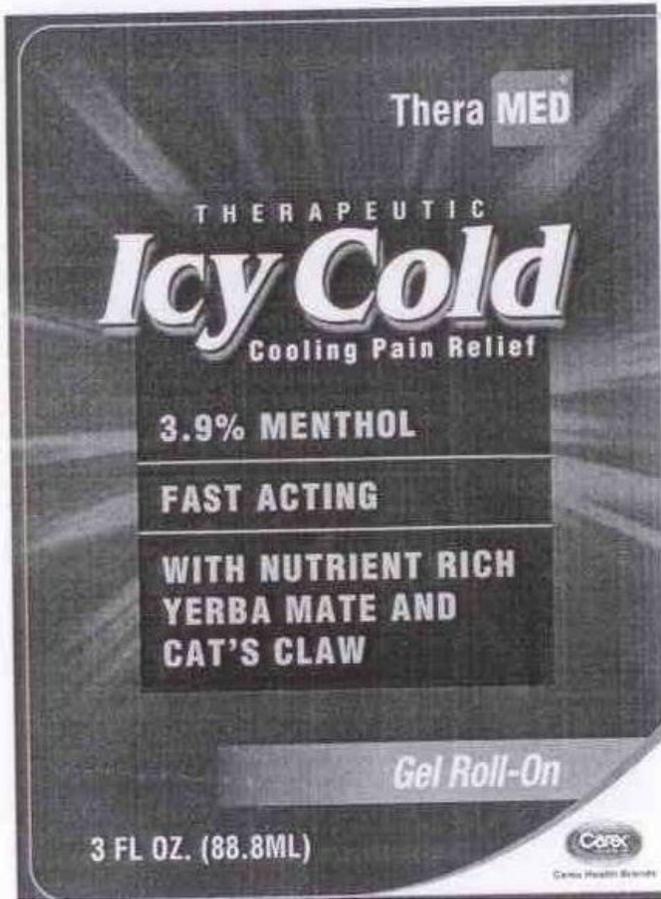
IF ACCIDENTALLY INGESTED, SEEK MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

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

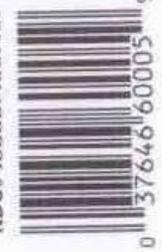


| Drug Facts | |
|---|---------------------|
| Active Ingredient | Purpose |
| Natural Menthol 3.9%..... | Cooling Pain Relief |
| Uses temporary relief of | |
| <ul style="list-style-type: none"> ■ Arthritis ■ Backache ■ Strains/Sprains | |
| Warnings For external use only | |
| <p>Do not use near eyes, 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.</p> | |
| <p>Stop use and ask a doctor if irritation persists.</p> | |
| <p>Keep out of reach of children. If accidentally ingested, seek medical help or contact a Poison Control Center immediately.</p> | |
| <p>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.</p> | |
| <p>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</p> | |



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NDC# XXXXX-XXX-XX



THERAPEUTIC ICY COLD COOLING PAIN RELIEF ROLL-ON

menthol gel

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69851-101 |
| 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 |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0K00R) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CARBOMER 940 (UNII: 4Q93RCW27E) | |
| ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F) | |
| 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:69851-101-13 | 88.8 mL in 1 BOTTLE, WITH APPLICATOR; 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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