

IRELIEV ROLL ON COOL PAIN RELIEF- menthol gel

Excel Health, Inc

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.

iRELIEV Roll-On Cool Pain Relief Gel

Drug Facts

Active ingredient

Menthol 6%

Topical Analgesic

Indications:

For the temporary relief of minor aches and pains of the muscles and joints associated with arthritis, simple backache, sprains, bruises, and strains.

Warnings

For external use only

- Avoid contact with eyes
- If symptoms persist for more than seven days, discontinue use and consult physician.

Keep out of reach of children

If swallowed, consult physician

Do not apply

- to wounds or damaged skin
- Do not bandage tightly

If pregnant or breast feeding

contact physician prior to use

Directions

- Adults and children two-years of age or older: Apply to affected area not more than three to four times dail
- Children under two-years of age: consult a physician

Other information

store at room temperature

Inactive Ingredients

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arctium Lappa (Burdock) Root Extract, Arnica Montana Extract, Boswellia Serrata Extract, Calendula Officinalis Extract,

Camellia Sinensis (Green Tea) Extract, Carbomer, Ethylhexylglycerin, Glycerin, Ilex Paraguariensis (Yerba Mate') Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Extract, Phenoxyethanol, Polysorbate- 20, Tocopheryl Acetate (Vitamin E), Triethanolamine

Package Labeling:

Pain Gel
Vanishing Smell | Colorless | Paraben-Free | Long Lasting

iReliev[®]

Soothing Menthol
ROLL-ON
Cool Pain Relief

For arthritis, backache, sore muscles, and joints

Our Pain Relief Vision
At 14, my passion for all-natural pain relief started as I watched my Mom rely on traditional medicine. As the years went on, I set out to develop over the counter remedies that were easy on the pocket book and amazingly effective. The people I care most about use iReliev[®] products, so we strive each day to make them better. My goal, all-natural pain relief for all.

MIKE WILLIAMS
Founder & CEO

Distributed by:
ExcelHealth Inc.
1603 Hart St.
Southlake, TX 76092

iReliev.com
(855) 723-2582

3 oz. (88 ml) Model # TO-3RO

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Warnings
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- Avoid contact with eyes.
- For external use only.
- If symptoms persist for more than seven days, discontinue use and consult physician.
- **Keep out of reach of children.** If swallowed, consult physician.
- Do not apply to wounds or damaged skin.
- Do not bandage tightly.
- If pregnant or breast feeding, contact physician prior to use.

Directions

- Adults and children two-years of age or older: Apply to affected area not more than three to four times daily.
- Children under two-years of age: consult a physician.

Additional information
Store at room temperature.

Other ingredients
Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arctium Lappa (Burdock) Root Extract, Arnica Montana Extract, Boswellia Serrata Extract, Calendula Officinalis Extract, Camellia Sinensis (Green Tea) Extract, Carbomer, Ethylhexylglycerin, Glycerin, Ilex Paraguariensis (Yerba Mate') Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Extract, Phenoxyethanol, Polysorbate-20, Tocopheryl Acetate (Vitamin E), Triethanolamine.

IRELIEV ROLL ON COOL PAIN RELIEF

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72909-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength

ALOE VERA LEAF (UNII: ZY81Z83H0X)
WATER (UNII: 059QF0K00R)
ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3)
ARNICA MONTANA (UNII: O80TY208ZW)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
CARBOXYPOLYMETHYLENE (UNII: 0A5MMB07FC)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
GLYCERIN (UNII: PDC6A3C0OX)
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
MELISSA OFFICINALIS (UNII: YF70189L0N)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)
TROLAMINE (UNII: 9O3K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72909-014-01	88 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/20/2019	

Labeler - Excel Health, Inc (079213529)