

**MAXIMUM STRENGTH COLD SORE TREATMENT- maximum strength cold sore treatment gel**

**Meijer Distribution 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.*

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**Maximum Strength Cold Sore Treatment - Meijer**

Active ingredients Purpose

Camphor 3.00%

Menthol 1.00%

Phenol 1.50%

White Petrolatum 89.20%

Purpose

Cold sore/fever blister treatment

Cold sore/fever blister treatment

Cold sore/fever blister treatment

Skin Protectant

Uses

- For treatment of cold sores/fever blisters on the face or lips
- Temporarily relieves the symptoms of itching and pain associated with cold sores/fever blisters
- Temporarily protects minor cuts, scrapes, burns, and sores
- Helps prevent and temporarily protects chapped or cracked skin and lips

Warnings

For external use only: Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites or serious burns, consult a physician.

Allergy alert: Do not use if you are allergic to any of the ingredients in this product.

When using this product avoid contact with eyes. Use only as directed.

Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than 1 week unless

directed by a doctor.

Other information store at room temperature

Inactive ingredients Eucalyptol, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Thymol,

Tocopheryl Nicotinate

Questions or comments?

Call us toll-free at 1-877-242-3234 Monday-Friday, 9 a.m. to 5 p.m. EST.

Serious side effects associated with use of this product may be reported to this number.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

at 1-800-222-1222.

Directions

- Clean the affected area • Apply a small amount of this product to the affected area 1 to 3 times daily
- Rub in gently • May be covered with a sterile bandage • Wash hands before and after applying cream
- Do not share this product with anyone • Children under 12 years of age: ask a doctor

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**Cold Sore Tube card PDP**

Maximum Strength

(Camphor 3.00%, Menthol 1.00%, Phenol 1.50%, White Petrolatum 89.20%)

Cold Sore Treatment

Medicated

Temporary Relief of Pain and Discomfort

Works on Contact

Applied Clear

Phthalate Free\*\*

Paraben Free\*

Sulfate Free

With Tea Tree Oil

Cold Sore / Fever Blister treatment & Skin Protectant

NET WT 0.07 OZ ( 2.0 g)

\*Free from Methylparaben, Ethylparaben, Propylparaben and Butylparaben

\*\*tested per CPSC-CH-C1001.09.3

DIST. BY MEIJER

DISTRIBUTION, INC.

GRAND RAPIDS, MI 49544

[www.meijer.com](http://www.meijer.com)



## MAXIMUM STRENGTH COLD SORE TREATMENT

maximum strength cold sore treatment gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41250-411
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	892 mg in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	30 mg in 1 g
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	15 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
TOCOPHERYL NICOTINATE, D-.ALPHA. (UNII: W1I5UCY5C)	
THYMOL (UNII: 3J50XA376E)	
EUCALYPTOL (UNII: RV6J6604TK)	

MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-411-01	2 g in 1 TUBE; Type 0: Not a Combination Product	09/09/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/09/2019	

**Labeler** - Meijer Distribution Inc. (006959555)

**Registrant** - Ranir LLC (364567615)

### Establishment

Name	Address	ID/FEI	Business Operations
Accupac, Inc		071609663	manufacture(41250-411) , analysis(41250-411) , label(41250-411)

### Establishment

Name	Address	ID/FEI	Business Operations
Ranir LLC		364567615	pack(41250-411) , label(41250-411) , repack(41250-411)

Revised: 12/2019

Meijer Distribution Inc.