

**TRURELIEF RUBITON RUB IT WHERE IT HURTS- menthol cream**  
**Cosmetic Specialty Labs, 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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**Active Ingredient**

Menthol, 3.0%

**Purpose**

Topical analgesic

**Uses**

temporarily relieves minor pain associated with: • arthritis • simple backache • muscle strains • sprains • bruises • cramps

**Warnings**

for external use only

**When using this product**•use only as directed •do not bandage tightly or use with heating pad •avoid contact with eyes or mucous membranes •do not apply to wounds or damaged skin

**Stop use and ask a doctor if**• condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days • redness is present • irritation develops

**If pregnant or breast-feeding,** ask a health professional before use.

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

**Directions:**

**Adults and children over 12 years:**• apply generously to affected area • massage into painful area until thoroughly absorbed into skin • repeat as necessary, but no more than 4 time daily

**Children 12 years or younger:** ask a doctor

**Inactive ingredients**

Aloe Barbadensis Leaf Juice, Anthemis nobilis (Roman Chamomile), Arnica montana

Flower Extract, Butylene Glycol, Calendula officinalis (Marigold), Caprylyl Glycol, Capsicum frutescens Fruit, Carbomer, Centaurea cyanus (Cornflower), Cetearyl Alcohol, Chamomilla recutita (Matricaria Chamomilla), Coriandrum sativum (Coriander) Fruit Oil, Emu Oil, Fragrance, Hamamelis virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Hypericum perforatum (St. John's Wort), Methylsulfonylmethane, Phenoxyethanol, Purified Water, Salix alba (Willow) Bark Extract, SD Alcohol 40, Sorbitol, Tetrasodium EDTA, Tilia cordata (Lime Tree), Triethanolamine.

## Package Label

**Drug Facts**

Active Ingredient	Purpose
Menthol 3.0%	Topical analgesic

**Uses** temporarily relieves minor pain associated with: ■ arthritis ■ simple backache ■ muscle strains ■ sprains ■ bruises ■ cramps

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**Inactive Ingredients:** Aloe Barbadosis Leaf Juice, Anthemis nobilis (Roman Chamomile), Amica montana Flower Extract, Butylene Glycol, Calendula officinalis (Marigold), Caprylyl Glycol, Capsicum frutescens Fruit, Carbomer, Centaurea cyanus (Cornflower), Cetearyl Alcohol, Chamomilla recutita (Matricaria Chamomilla), Coriandrum sativum (Coriander) Fruit Oil, Emu Oil, Fragrance, Hamamelis virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Hypericum perforatum (St. John's Wort), Methylsulfonylmethane, Phenoxyethanol, Purified Water, Salix alba (Willow) Bark Extract, SD Alcohol 40, Sorbitol, Tetrasodium EDTA, Tilia cordata (Lime Tree), Triethanolamine.

PLEASE RECYCLE  
 NEVER  
 ANIMAL TESTED

NDC# 58133-451-04      3738001

Manufactured for:  
 RubitOn, LLC  
 20412 Arapais Ave  
 Orange, CA 92668

## TRURELIEF RUBITON RUB IT WHERE IT HURTS

menthol cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58133-451
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CAPSICUM</b> (UNII: 00UK7646FG)	
<b>EMU OIL</b> (UNII: 344821WD61)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>CORIANDER OIL</b> (UNII: 7626GC95E5)	
<b>TILIA CORDATA FLOWER</b> (UNII: CFN6G1F6YK)	
<b>DEHYDRATED ALCOHOL</b> (UNII: 3K9958V90M)	
<b>HAMAMELIS VIRGINIANA TOP</b> (UNII: UDA30A2JJY)	
<b>HYPERICUM PERFORATUM</b> (UNII: XK4IUX8MNB)	
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)	
<b>SALIX ALBA BARK</b> (UNII: 205MXS71H7)	
<b>EDETATE SODIUM TETRAHYDRATE</b> (UNII: L13NHD21X6)	
<b>CHAMAEMELUM NOBILE FLOWER</b> (UNII: O2T154T6OG)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>CENTAUREA CYANUS FLOWER</b> (UNII: QZ239038YC)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-451-04	88 mL in 1 TUBE; Type 0: Not a Combination Product	02/08/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/08/2022	

**Labeler** - Cosmetic Specialty Labs, Inc. (032973000)

**Establishment**

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty Labs, Inc.		032973000	manufacture(58133-451) , pack(58133-451) , label(58133-451) , analysis(58133-451)

Revised: 2/2022

Cosmetic Specialty Labs, Inc.