# PAIN RELIEF LIQUID ROLLER- camphor 3.5%, menthol 3.5% liquid Tommie Copper, 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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## **Pain Relief Liquid Roller**

Camphor 3.5%, Menthol 3.5%

## Topical Analgesic

For the temporary relief of minor aches and pain associated with simple backaches, arthritis, strains, bruises, and sprains.

**For external use only. Flammable--**Do not use while smoking or near heat or flame. **When using this product** avoid contact with eyes, do not apply to wounds or damaged skin, and do not bandage tightly. **Stop use and ask a doctor if** condition worsens, if symptoms persist for more than 7 days or clear up and occur again within a few days.

## If pregnant or breast-feeding ask a health professional.

If swallowed, get medical help or contact a Poison Control Center right away.

Adults and children 12 years of age and older, apply to the affected area not more than 3 to 4 times daily.

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis (Aloe Vera) Leaf Extract, Aminomethyl Propanol, Arnica Montana (Arnica) Flower Extract, Calendula Officinalis (Marigold) Flower Extract, Camellia Sinensis (Green Tea) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Cucumis Sativus (Cucumber) Fruit Extract, Echinacea Angustifolia (Coneflower) Extract, Ethyhexylglycerin, Eucalyptus Globulus (Eucalyptus) Leaf Oil, FD&C Blue No 1, Glycerin, Ilex Paraguariensis (Yerba Mate) Leaf Extract, Isopropyl Alcohol, Juniperus Communis (Juniper) Fruit Extract, Mentha Piperita (Peppermint) Oil, Phenoxyethanol, Water.



COOLING

# MENTHOL \* CAMPHOR

# PAIN RELIEF LIQUID ROLLER

- **+ CUCUMBER**
- PEPPERMINT

Temporary relief for minor pain from arthritis, backaches, joint & muscle pain

NET WT 2.5 OZ (70g)

**TOMMIECOPPER** 

## Drug Facts

Active ingredients	Purpose
Camphor 3.5%	Topical analgesic
Menthol 3.5%	Topical analgesic

 $\pmb{\textit{Uses}}$  For the temporary relief of minor aches and pain associated with • simple backache • arthritis • strains • bruises • sprains.

#### Warnings

For external use only.

Flammable - Do not use while smoking or near heat or flame.

When using this product • avoid contact with eyes • do not apply to wounds or damaged skin • do not bandage tightly.

Stop use and ask a doctor if • condition worsens • if symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast-feeding ask a health professional.

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

**Directions** • adults and children 12 years of age and older, apply to affected area not more than 3 to 4 times daily.

Inactive ingredients Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis (Aloe Vera) Leaf Extract, Aminomethyl Propanol, Amica Montana (Arnica) Flower Extract, Calendula Officinalis (Marigold) Flower Extract, Camellia Sinensis (Green Tea) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Cucumis Sativus (Cucumber) Fruit Extract, Echinacea Angustifolia (Coneflower) Extract, Ethylhexylglycerin, Eucalyptus Globulus (Eucalyptus) Leaf Oil, FD&C Blue No. 1, Glycerin, Ilex Paraguariensis (Yerba Mate) Leaf Extract, Isopropyl Alcohol, Juniperus Communis (Juniper) Fruit Extract, Mentha Piperita (Peppermint) Oil, Phenoxyethanol, Water.



THIS PRODUCT DOES NOT CONTAIN COPPER.

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# **PAIN RELIEF LIQUID ROLLER**

camphor 3.5%, menthol 3.5% liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72562-167

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

Active ingredient/Active Piolety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.5 g in 100 g	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3.5 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)		

ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)

**EUCALYPTUS OIL (UNII: 2R040NI662)** 

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
JUNIPER BERRY (UNII: O84B5194RL)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CUCUMBER (UNII: YY7C30VXJT)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMOMILE (UNII: FGL3685T2X)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:72562- 167-25	70 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/19/2021	

# Labeler - Tommie Copper, Inc. (081176569)

# Registrant - Derma Care Research Labs, LLC (116817470)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Derma Care Research Labs, LLC		116817470	manufacture(72562-167)	

Revised: 1/2023 Tommie Copper, Inc.