

**TOMMIE COPPER PAIN RELIEF 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.

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, 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, Phenoxyethanol, Water



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MOUNT KISCO, NEW YORK 10549 • 1855.692.8291

Drug Facts	Purpose
Active ingredients Camphor 3.5% Menthol 3.5%	Topical analgesic Topical analgesic
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.	
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, Arnica Montana (Arnica) Flower Extract, Calendula Officinalis (Marigold) Flower Extract, Camellia Sinensis (Green Tea) Leaf Extract, Chamomilla Recutita (Matricaria) Flower 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, Phenoxyethanol, Water.	

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PAIN RELIEF LIQUID ROLLER

TOMMIECOPPER

COOLING MENTHOL + CAMPHOR

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



ALOE



CHAMOMILE

NET WT 3 OZ (85 g)

Drug Facts

Active ingredients

Camphor 3.5%	Topical analgesic
Menthol 3.5%	Topical analgesic

Purpose

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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, Arnica Montana (Arnica) Flower Extract, Calendula Officinalis (Marigold) Flower Extract, Camellia Sinensis (Green Tea) Leaf Extract, Chamomilla Recutita (Matricaria) Flower 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, Phenoxyethanol, Water.

THIS PRODUCT DOES NOT CONTAIN COPPER.

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TOMMIE COPPER PAIN RELIEF ROLLER

camphor 3.5%, menthol 3.5% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72562-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
GLYCERIN (UNII: PDC6A3C0OX)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)
CALENDULA ARVENSIS LEAF (UNII: 3U3U118F2L)
MATRICARIA CHAMOMILLA FLOWERING TOP OIL (UNII: SA8AR2W4ER)
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8)
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
JUNIPER BERRY (UNII: O84B5194RL)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72562-105-03	85 g in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2020	
2	NDC:72562-105-01	28 g in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/30/2020	

Labeler - Tommie Copper, Inc. (081176569)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs, LLC		116817470	manufacture(72562-105)

Revised: 1/2023

Tommie Copper, Inc.