

**TOMMIE COPPER PAIN RELIEF MAXIMUM STRENGTH- trolamine salicylate 10% cream
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 Cream, Trolamine Salicylate 10%

Trolamine Salicylate 10%

Topical Analgesic.

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

For external use only.

Allergy Alert: if prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

When using this product use only as directed, avoid taking a bath or shower within 1 hour before or after applying, do not bandage or use with a 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 or symptoms persist for more than 7 days, if symptoms clear up and occur again within a few days.

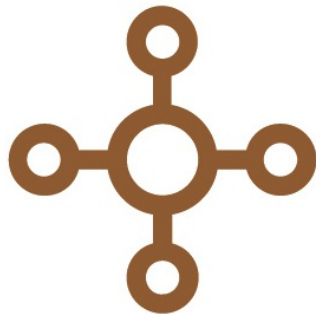
If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children.

Adults and children 12 years of age: apply generously to the affected area, massage into painful area until thoroughly absorbed into the skin, repeat as necessary, but not more than 3 to 4 times daily.

Children under 12 years of age: ask a doctor.

Aloe Barbadensis (Aloe Vera) Leaf Extract, Arnica Montana (Arnica) Flower Extract, Calendula Officinalis (Marigold) Flower Extract, Camellia Sinensis (Green Tea) Leaf Extract, Cetyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Echinacea Angustifolia (Coneflower) Extract, Glycerin, Ilex Paraguariensis (Yerba Mate) Leaf Extract, Juniperus Communis (Juniper) Fruit Extract, Methylparaben, Mineral Oil, Potassium Phosphate, Propylparaben, Stearic Acid, Triethanolamine, Water.



PAIN RELIEF CREAM

TOMMIECOPPER

MAXIMUM STRENGTH

Trolamine Salicylate 10%

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



ALOE



CHAMOMILE

NET WT 3 OZ (85g)

Drug Facts

Active ingredient Purpose

Trolamine Salicylate 10% ...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.

Allergy alert: If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

When using this product • use only as directed • do not bandage tightly or use with a 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 • 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 or older: apply generously to affected area • massage into painful area until thoroughly absorbed into the skin • repeat if necessary, but no more than 4 times daily
children under 2 years of age: ask a doctor.

Inactive ingredients

Aloe Barbadensis (Aloe Vera) Leaf Extract, Arnica Montana (Arnica) Flower Extract, Calendula Officinalis (Marigold) Flower Extract, Camellia Sinensis (Green Tea) Leaf Extract, Cetyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Echinacea Angustifolia (Coneflower) Extract, Glycerin, Ilex Paraguariensis (Yerba Mate) Leaf Extract, Juniperus Communis (Juniper) Fruit Extract, Methylparaben, Mineral Oil, Potassium Phosphate, Propylparaben, Stearic Acid, Triethanolamine, Water.

THIS PRODUCT DOES NOT
CONTAIN COPPER.

DISTRIBUTED BY:
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MOUNT KISCO,
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TOMMIE COPPER PAIN RELIEF MAXIMUM STRENGTH

trolamine salicylate 10% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72562-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TROLAMINE SALICYLATE (UNII: H8O4040BHD) (SALICYLIC ACID - UNII:O414PZ4LPZ)	TROLAMINE SALICYLATE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
JUNIPER BERRY (UNII: O84B5194RL)	
CHAMOMILE (UNII: FGL3685T2X)	
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72562-103-03	85 g in 1 TUBE; Type 0: Not a Combination Product	12/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/14/2020	

