

COOL AND HEAT SORE MUSCLE ROLLER- menthol gel

Acutens

Acutens - Cool & Heat (80551-002)

Sore Muscle Roller

Active ingredients

Menthol 16%

Purpose

Topical Analgesic

Uses:

Temporary relief of minor aches pains of muscles and joints associated with arthritis, simple backache, strains, bruises, and sprains

Warnings

For external use only

Flammable: Keep away from fire or flame.

When using this product • use only as directed • do not bandage tightly or use with a heating pad • avoid contact with eyes and mucous membranes • do not apply to wounds or damaged, broken or irritated skin • a transient burning sensation may occur upon application but generally disappears in several days • if severe burning sensation occurs, discontinue use immediately • do not expose the area treated with product to heat or direct sunlight.

Stop use and ask doctor if • condition worsens • 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 before use.

Keep out of reach of children. If accidentally ingested get medical help or contact a Poison Control Center immediately

Direction

- Adults and children 2 years of age and older: apply to affected area not more than 3-4 times daily
- Children under 2 years old: consult apfysician

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer
 Capsaicin
 Glycerin
 Isopropyl Myristate
 Propylene Glycol
 SD Alcohol 40 (30.0%)
 Triethanolamine
 Water

NDC# 80551-002-02

COOL & HEAT SORE MUSCLE ROLLER



- Pain Relief Therapy for Arthritis, Backache, Muscle Strains & Sprains
- Non-Greasy
- Quick Drying
- No-Mess Applicator

Topical Analgesic
MAXIMUM STRENGTH
16% menthol



NET WT 2.5 OZ (70.8 G)

Drug Facts

Active ingredient	Purpose
Menthol 16%.....	Topical analgesic

Uses For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains.

Warnings

For external use only.

Flammable • keep away from fire or flame.

When using this product • use only as directed • do not bandage tightly or use with a heating pad • avoid contact with eyes and mucous membranes • do not apply to wounds or damaged, broken or irritated skin • a transient burning sensation may occur upon application but generally disappears in several days • if severe burning sensation occurs, discontinue use immediately • do not expose the area treated with product to heat or direct sunlight.

Stop use and ask doctor if • condition worsens • 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 before use. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily. Children under 2 years of age consult a physician.

Inactive ingredients Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Capsaicin, Glycerin, Isopropyl Myristate, Propylene Glycol, SD Alcohol 40 (30%), Triethanolamine, Water.

Questions? (917) 745-3082

MANUFACTURED FOR: ACTUENS, INC. SHERIDAN, WY 82801 | MANUFACTURED IN USA www.gosensiv.com support@gosensiv.com

COOL AND HEAT SORE MUSCLE ROLLER

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80551-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	16 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CAPSAICIN (UNII: S07O44R1ZM)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALCOHOL (UNII: 3K9958V90M)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80551-002-02	70.8 g in 1 CONTAINER; Type 0: Not a Combination Product	03/10/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/10/2021	

Labeler - Acutens (051133165)

Revised: 1/2024

Acutens