THERAWORX RELIEF FOR MUSCLE CRAMPS ROLL-ON- magnesium sulfate, unspecified form aerosol AVADIM HOLDINGS, INC.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Theraworx Relief for Muscle Cramps Roll-On

Drug Facts

Active Ingredient

Contains Magnesium Sulfate (*Magnesia sulphurica*)6X 0.05% HPUS The letters H.P.U.S. indicate that the componets in this product are officially monograped in the Homepathic Pharmacopoeia of the United States.

Purpose

Muscle Soreness Relief

Uses

- prevents cramps and spasms
- releases muscle tightness
- relieves muscle soreness

Warnings

For external use only. If eye contact occurs, rinse thoroughly with water.

When using this product

- avoid eye contact
- store between 32°F and 120°F
- use only as directed
- not for ingestion

Stop use and ask a doctor if

unintended effects occur.

If pregnant or breastfeeding,

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

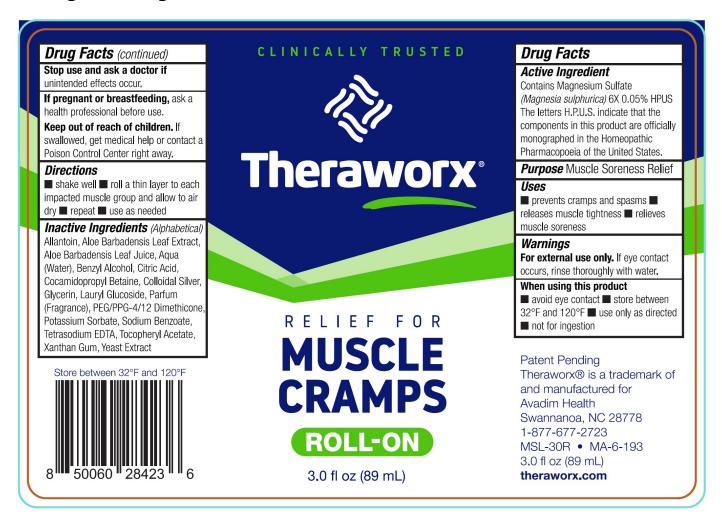
- shake well
- roll a thin layer to each impacted muscle group and allow to air dry
- repeat
- use as needed

Inactive Ingredients

(Alphabetical) Allantoin, Aloe Barbadensis Leaf Extract, Aloe Barbadensis Leaf Juice, Aqua (Water), Benzyl Alcohol, Citric Acid, Cocamidopropyl Betaine, Colloidal Silver, Glycerin, Lauryl Glucoside, Parfum (Fragrance), PEG/PPG-4/12 Dimethicone, Potassium Sorbate, Sodium Benzoate, Tetrasodium EDTA, Tocopheryl Acetate, Xanthan Gum, Yeast Extract

Store between 32°F and 120°F

Package Labeling:



THERAWORX RELIEF FOR MUSCLE CRAMPS ROLL-ON

magnesium sulfate, unspecified form aerosol

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61594-046

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	MAGNESIUM SULFATE,	6 [hp_X]

Inactive Ingredients	
Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
SILVER (UNII: 3M4G523W1G)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
PEG/PPG-4/12 DIMETHICONE (UNII: JAN3585W85)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61594-046- 00	1 in 1 CARTON	01/01/2025	
1		89 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		01/01/2025		

Labeler - AVADIM HOLDINGS, INC. (118512488)

Establishment					
Name	Address	ID/FEI	Business Operations		
AVADIM HOLDINGS, INC.		118512488	manufacture(61594-046)		

Revised: 9/2024 AVADIM HOLDINGS, INC.