THERAWORX RELIEF MUSCLE CRAMP AND SPASM RELIEF- magnesium sulfate heptahydrate spray, metered 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 Muscle Cramp and Spasm Relief Spray

Drug Facts

Active Ingredient

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

Purpose

Muscle Soreness Relief

Uses

- prevents muscle cramps
- releases muscle tightness
- reduces muscle soreness

Warnings

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

When using this product

• avoid eye contact • do not store at temperature above 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.

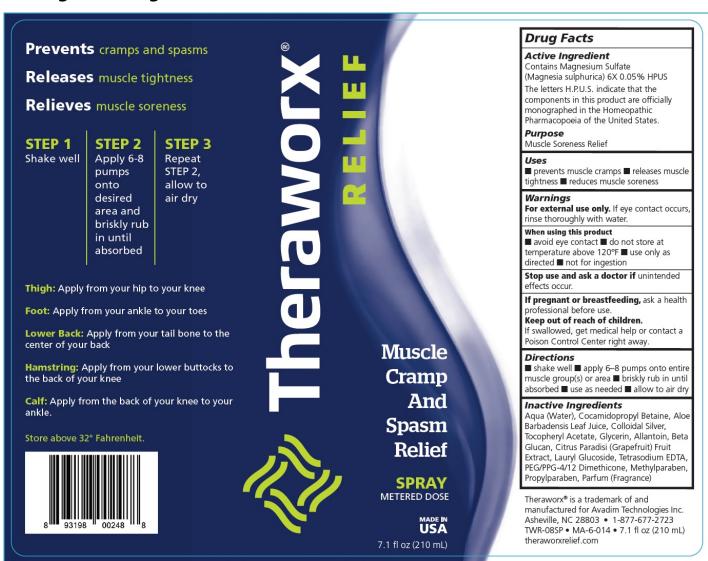
Directions

• shake well • apply 6-8 pumps onto entire muscle group(s) or area • briskly rub in until absorbed • use as needed • allow to air dry

Inactive Ingredients

Aqua (Water), Cocamidopropyl Betaine, Aloe Barbadensis Leaf Juice, Colloidal Silver, Tocopheryl Acetate, Glycerin, Allantoin, Beta Glucan, Citrus Paradisi (Grapefruit) Fruit Extract, Lauryl Glucoside, Tetrasodium EDTA, PEG/PPG-4/12 Dimethicone, Methylparaben, Propylparaben, Parfum (Fragrance)

Package Labeling:



THERAWORX RELIEF MUSCLE CRAMP AND SPASM RELIEF

magnesium sulfate heptahydrate spray, metered

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:61594-004

Route of Administration

TOPICAL

Active Ingredient/Active Moiety
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Active ingredient, Active Molecy		
Ingredient Name	Basis of Strength	Strength
MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE HEPTAHYDRATE	6 [hp_X] in 210 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SILVER (UNII: 3M4G523W1G)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALLANTOIN (UNII: 344S277G0Z)	
GRAPEFRUIT (UNII: O82C39RR8C)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
EDETATE SODIUM (UNII: MP1J8420LU)	
PEG/PPG-4/12 DIMETHICONE (UNII: JAN3585W85)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:61594- 004-00	210 mL in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	07/22/2017	

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
	07/22/2017		
	• •	Citation Date	

Labeler - AVADIM HOLDINGS, INC (118512488)

Registrant - AVADIM HOLDINGS, INC (118512488)

Revised: 4/2023 AVADIM HOLDINGS, INC