

**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 Homeopathic 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:

<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if unintended effects occur.</p> <p>If pregnant or breastfeeding, ask a health professional before use.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <p>■ shake well ■ roll a thin layer to each impacted muscle group and allow to air dry ■ repeat ■ use as needed</p> <p>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</p>	<p>CLINICALLY TRUSTED</p>  <p>Theraworx[®]</p> <p>RELIEF FOR MUSCLE CRAMPS</p> <p>ROLL-ON</p> <p>3.0 fl oz (89 mL)</p>	<p>Drug Facts</p> <p>Active Ingredient Contains Magnesium Sulfate (<i>Magnesia sulphurica</i>) 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.</p> <p>Purpose Muscle Soreness Relief</p> <p>Uses</p> <p>■ prevents cramps and spasms ■ releases muscle tightness ■ relieves muscle soreness</p> <p>Warnings For external use only. If eye contact occurs, rinse thoroughly with water.</p> <p>When using this product</p> <p>■ avoid eye contact ■ store between 32°F and 120°F ■ use only as directed ■ not for ingestion</p>
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Store between 32°F and 120°F



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Patent Pending
Theraworx[®] is a trademark of and manufactured for Avadim Health Swannanoa, NC 28778
1-877-677-2723
MSL-30R • MA-6-193
3.0 fl oz (89 mL)
theraworx.com

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 CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE, UNSPECIFIED FORM	6 [hp_X] in 1 mL

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: 5OCF3O11KX)	
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)	
.ALPHA.-TOCOPHEROL 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.