**THERAWORX RELIEF MUSCLE CRAMP AND SPASM RELIEF- magnesium sulfate heptahydrate aerosol, foam**
**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.*

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**Theraworx Relief Muscle Cramp and Spasm Relief Foam**

## *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.

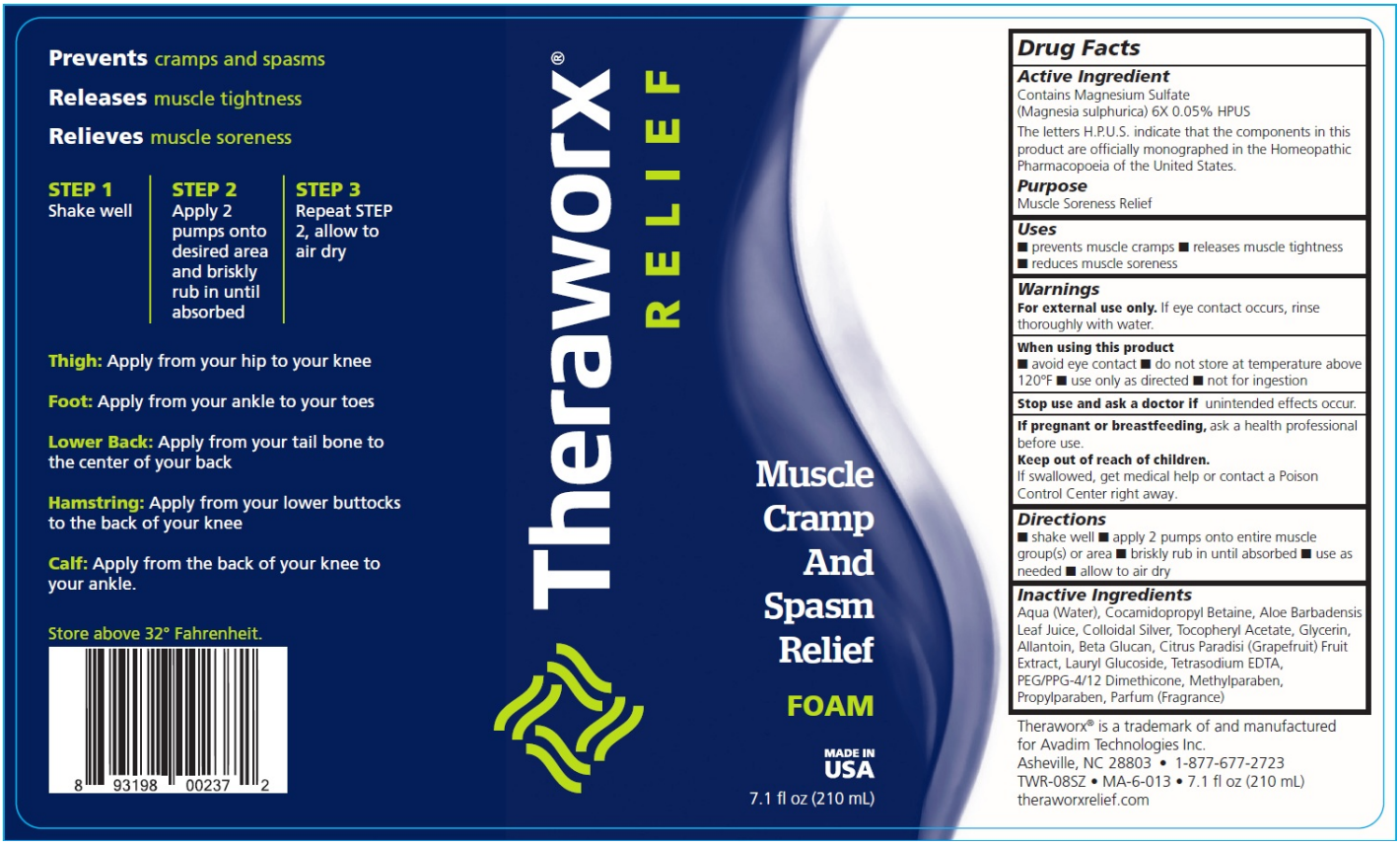
### *Directions*

• shake well • apply 2 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 aerosol, foam

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:61594-003 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **MAGNESIUM SULFATE HEPTAHYDRATE** (UNII: SK47B8698T) | MAGNESIUM SULFATE | 6 [hp_X] |

| | | |
|---|---|---|
| (MAGNESIUM CATION - UNII:T6V3LHY838) | HEPTAHYDRATE | in 210 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **WATER** (UNII: 059QF0KO0R) | |
| **COCAMIDOPROPYL BETAINE** (UNII: 5OCF3O11KX) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **SILVER** (UNII: 3M4G523W1G) | |
| **.ALPHA.-TOCOPHEROL 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) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:61594-003-00 | 210 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/22/2017 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved homeopathic | | 07/22/2017 | |

## Labeler - AVADIM HOLDINGS, INC. (118512488)

## Registrant - AVADIM HOLDINGS, INC. (118512488)

Revised: 4/2023 AVADIM HOLDINGS, INC.