PHUEL- magnesium sulfate heptahydrate solution 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.

PHUEL 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

- activate muscle function
- release muscle tightness
- reduce 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° and 120° Fahrenheit
- 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.

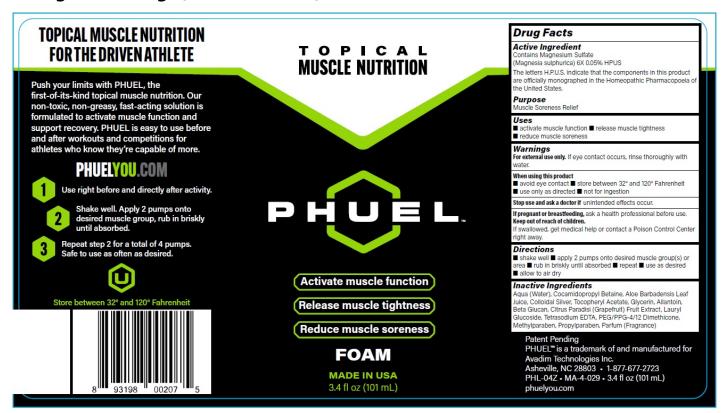
Directions

- shake well
- apply 2 pumps onto desired muscle group(s) or area
- rub in briskly until absorbed
- repeat
- use as desired
- allow to air dry

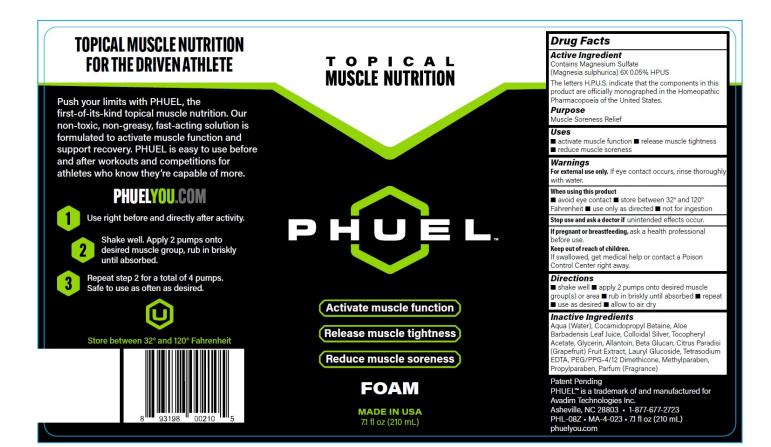
Inactive Ingredients

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)

Packgae Labeling: (61594-010-03)



Packgae Labeling: (61594-010-07)



PHUEL

magnesium sulfate heptahydrate solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61594-010

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T) (MAGNESIUM MAGNESIUM SULFATE CATION - UNII:T6V3LHY838)

MAGNESIUM SULFATE HEPTAHYDRATE | 6 [hp_X] in 1 mL

Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0KOOR) COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX) ALOE VERA LEAF (UNII: ZY81Z83H0X) SILVER (UNII: 3M4G523W1G) GLYCERIN (UNII: PDC6A3C0OX) ALLANTOIN (UNII: 344S277G0Z) GRAPEFRUIT (UNII: 082C39RR8C) 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- 010-03 | 101 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 11/07/2018 | | | | |
| 2 | NDC:61594- 010-07 | 210 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 11/07/2018 | | | | |

| Marketing Information | | | | | | |
|---------------------------|---|-------------------------|-----------------------|--|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | | |
| unapproved homeopathic | | 11/07/2018 | | | | |
| | | | | | | |

Labeler - AVADIM HOLDINGS, INC. (118512488)

Registrant - AVADIM HOLDINGS, INC. (118512488)

| Establishment | | | | | | |
|-----------------------|---------|-----------|----------------------------|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | |
| AVADIM HOLDINGS, INC. | | 118512488 | manufacture(61594-010) | | | |

Revised: 4/2023 AVADIM HOLDINGS, INC.