THERAWORX RELIEF FOR FOOT CRAMPS FOAM- magnesium sulfate, unspecified form 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.

Theraworx Relief for Foot Cramps 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 cramps and spasms
- releases muscle tightness
- relieves muscle sorenss

Warnings

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

When using this product

- avoid eye contact
- store between 32ºF and 120ºF
- ues only as directed
- not for ingestion

Stop use and ask a doctor if

unintended effects occurs.

If pregnant or breastfeeding,

ask a health professional before use.

Keep out of reach of chidlren.

If swallowed, get medical help or contact a Poison Control right away.

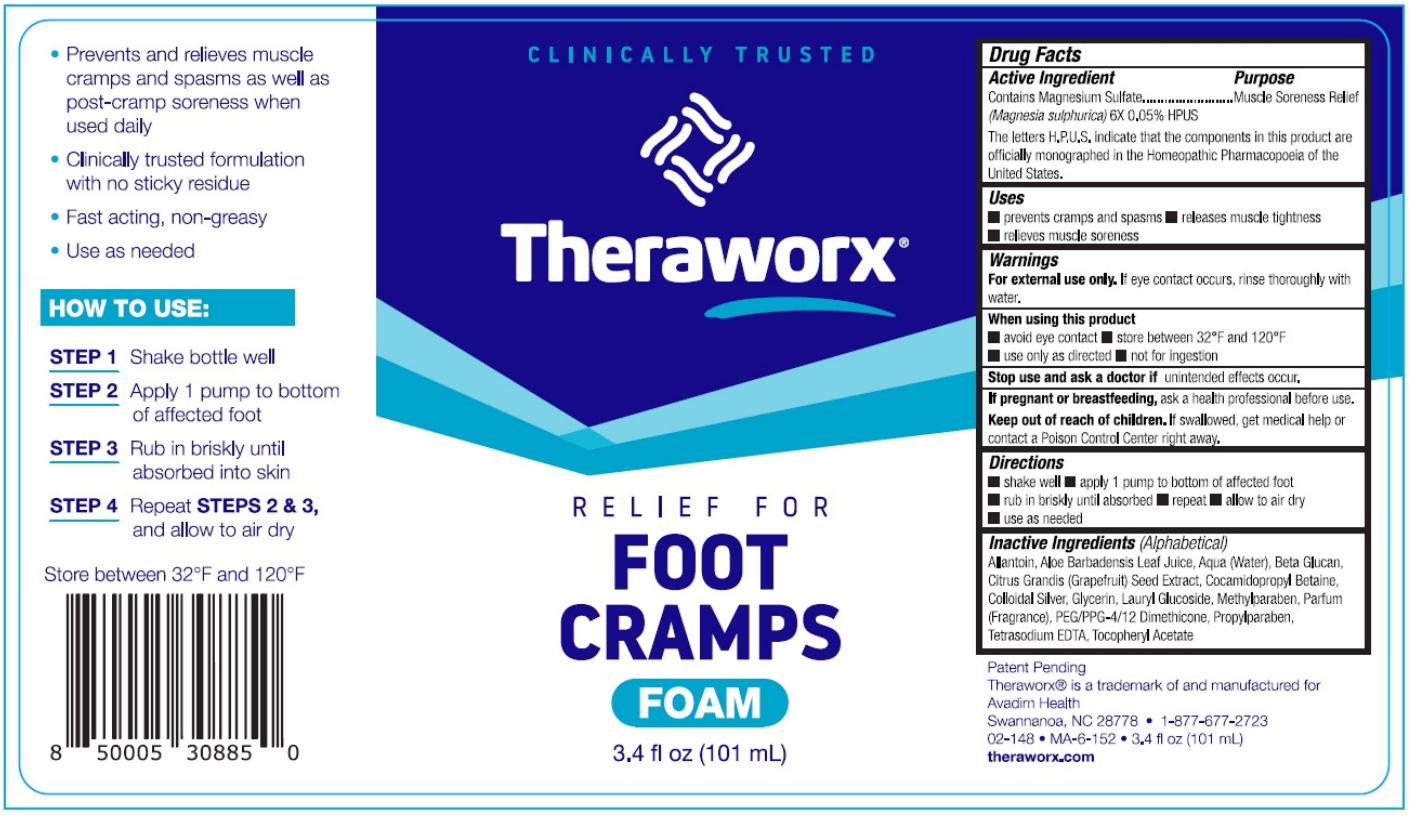
Directions

- shake well
- apply 1 pump to bottom of affected foot
- rub in briskly until absorbed
- repeat
- allow to air dry
- use as needed

Inactive Ingredients (Alphabetical)

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

Package Labeling:



THERAWORX RELIEF FOR FOOT CRAMPS FOAM

magnesium sulfate, unspecified form aerosol, foam

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61594-021

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)	
CITRUS MAXIMA SEED (UNII: 083X55C543)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SILVER (UNII: 3M4G523W1G)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG/PPG-4/12 DIMETHICONE (UNII: JAN3585W85)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61594-021-00	101 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/01/2022	

Labeler - AVADIM HOLDINGS, INC. (118512488)

Registrant - AVADIM HOLDINGS, INC. (118512488)

Establishment

Name	Address	ID/FEI	Business Operations
AVADIM HOLDINGS, INC.		118512488	manufacture(61594-021)