THERAWORX PATENTED FOAM FORMULATION- allantoin liquid Avadim Health, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Theraworx Patented Foam Formulation

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Active Ingredient:

Allantoin 0.5%

Purpose

Skin Protectant

Uses:

• For temporary Protection of minor cuts, scrapes, burns, and chapped or cracked skin.

Warning:

• For external use only.

Keep out of reach of children.

Do not use in the eyes.

- Do not use on deep or puncture wounds, animal bites, or serious burns.
- Extended use may increase risk of sunburn.

Stop use and ask doctor

if condition worsens or symptoms last more than seven days.

Directions:

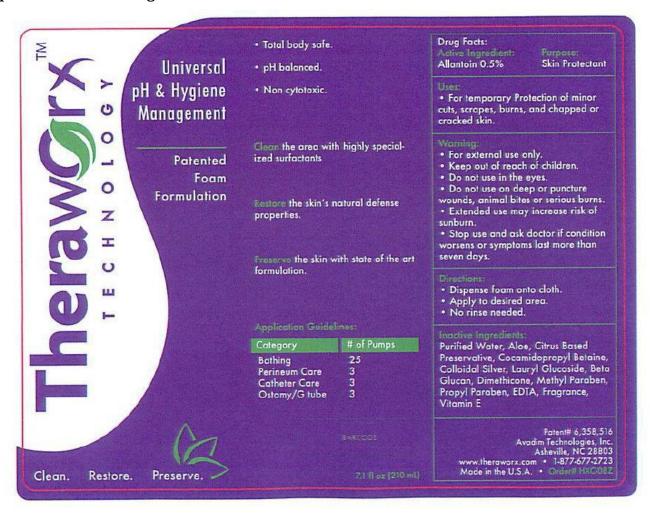
- Dispense foam onto cloth.
- Apply to desired area.
- No rinse needed.

Inactive Ingredients:

Purified Water, Aloe, Citrus Based Preservative, Cocamidopropyl Betaine, Colloidal Silver, Lauryl Glucoside, Beta Glucan, Dimethicone, Methyl Paraben, Propyl Paraben, EDTA, Fragrance, Vitamin E

Theraworx Patented Foam Formulation 50ml (61594-001-00) | Theraworx Patented Foam Formulation 109ml (61594-001-01) | Theraworx Patented Foam Formulation 210ml (61594-001-02)

Representative Labeling



THERAWORX PATENTED FOAM FORMULATION

allantoin liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61594-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALLANTO IN (UNII: 344S277G0Z) (ALLANTO IN - UNII:344S277G0Z)	ALLANTOIN	5 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
ALOE (UNII: V5VD430 YW9)			
CO CAMIDO PRO PYL BETAINE (UNII: 50 CF30 11 KX)			
SILVER (UNII: 3M4G523W1G)			
LAURYL GLUCO SIDE (UNII: 76LN7P7UCU)			

DIMETHICO NE (UNII: 92RU3N3Y1O)	
METHYLPARABEN (UNII: A218 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETIC ACID (UNII: 9G34HU7RV0)	
.ALPHATO COPHEROL (UNII: H4N855PNZ1)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61594-001-00	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/09/2014	
2	NDC:61594-001-01	109 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 9 /20 14	
3	NDC:61594-001-02	210 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/09/2014	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	0 1/0 9 /20 14		

Labeler - Avadim Health, Inc. (041443877)

Establishment				
Name	Address	ID/FEI	Business Operations	
Avadim Health, Inc.		041443877	manufacture (6 159 4-0 0 1)	

Revised: 11/2019 Avadim Health, Inc.