

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



Universal pH & Hygiene Management

Patented Foam Formulation

- Total body safe.
- pH balanced.
- Non cytotoxic.

Clean the area with highly specialized surfactants

Restore the skin's natural defense properties.

Preserve the skin with state of the art formulation.

Application Guidelines:

Category	# of Pumps
Bathing	25
Perineum Care	3
Catheter Care	3
Ostomy/G tube	3

BARCODE

7.1 fl oz (210 mL)

Drug Facts:

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Patent# 6,358,516
Avadim Technologies, Inc.
Asheville, NC 28803
www.theraworx.com • 1-877-677-2723
Made in the U.S.A. • Order# HXC08Z

Clean. Restore. Preserve.

THERAWORX PATENTED FOAM FORMULATION

allanto in 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
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE (UNII: V5VD430YW9)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
SILVER (UNII: 3M4G523W1G)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	

DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
EDETIC ACID (UNII: 9G34HU7RV0)	
.ALPHA.-T O C P H E R O L (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	01/09/2014	
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	01/09/2014	

Labeler - Avadim Health, Inc. (041443877)

Establishment			
Name	Address	ID/FEI	Business Operations
Avadim Health, Inc.		041443877	manufacture(61594-001)

Revised: 11/2019

Avadim Health, Inc.