THERAWORX PROTECT ADVANCED HYGIENE WITH SKIN PROTECTANTallantoin cloth AVADIM HOLDINGS, INC.

Theraworx Protect Advanced Hygiene with Skin Protectant

Drug Facts

Active Ingredient

Allantoin 0.65%

Purpose

Skin Protectant

Uses

- temporarily protects minor:
- cuts
- scrapes
- burns
- temporarily protects chapped or cracked skin

Warnings

For external use only

Do not use

- on puncture wounds
- on animal bites
- on serious burns

When using this product

• do not get into eyes

Stop use and ask a doctor if:

- condition worsens
- symptoms last more then 7 days or clear up and occur again within a few days

If pregnant or breastfeeding,

ask a health professional before use.

Keep out of reach of children

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

Directions

• apply as needed

Other Information

- store between 32 F and 120 F
- do not use if seal is broken

Inactive Ingredients

(Alphabetical) Aloe barbadensis Leaf Extract, Aloe barbadensis Leaf juice, Aqua (water), 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 (Vitamin E), Yeast Extract

Package Labeling:



Theraworx Protect is safe for use on the skin, including the most sensitive areas. It can be applied all over the body, including the face, groin, and genital area.

SAFE FOR:

- Infants, children and adults
- Sensitive skin
- Mucous membranes
- Daily use, or as often as needed

COMMONLY USED FOR:

- Total body bathing for patients with allergies to harsh antiseptics or sensitive skin
- Critical care or ICU patients
- Bed-bound or isolation patients
- Q12 peri-care and foley catheter care processes
- Routine peri-care, after bowel movements
- Prior to and after catheter insertion

INSTRUCTIONS:

- Can be warmed for comfort (warmer temperature should not exceed 125° F)
- Cleanse with either side of towel
- No rinsing needed, simply allow to air dry
- Properly dispose of towel after use



Scan the QR code for detailed Instructions For Use on adults, children, and infants



theraworxpro.com/instructions-for-use

THERAWORX PROTECT ADVANCED HYGIENE WITH SKIN PROTECTANT

allantoin cloth

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:61594-036 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
WATER (UNII: 059QF0KO0R)		
GRAPEFRUIT (UNII: O82C39RR8C)		
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)		
SILVER (UNII: 3M4G523W1G)		
GLYCERIN (UNII: PDC6A3C0OX)		
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PEG/PPG-4/12 DIMETHICONE (UNII: JAN3585W85)		
PROPYLPARABEN (UNII: Z8IX2SC10H)		
EDETATE SODIUM (UNII: MP1J8420LU)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:61594-036- 00	8 in 1 CARTON	07/01/2024			
1		18 g in 1 POUCH; Type 0: Not a Combination Product				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	07/01/2024	

Labeler - AVADIM HOLDINGS, INC. (118512488)

Revised: 1/2024 AVADIM HOLDINGS, INC.