MOISTURE BARRIER- moisture barrier ointment ointment Unipack, 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.

Active Ingredient

Active Ingredient

White Petrolatum 98.3%

Purpose

Skin Protectant

Uses

Temporarily protects minor cuts, scrapes, and burns

Temporarily protects and helps relieve chapped or cracked skin

Helps treat and prevent diaper rash caused from wetness, urine and/or stool

Warnings

For external use only

Do not use on

Do not use on - deep or puncture wounds - animal bites - serious burns - an area that is infected

When using this product

When using this product - do not get into eyes

Stop use and ask a doctor if

Stop use and ask a doctor if - condition worsens - symptoms last for more than 7 days or clear up and occur again within a few days

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Gently cleanse and pat dry affected area

Apply as needed

Inactive ingredients

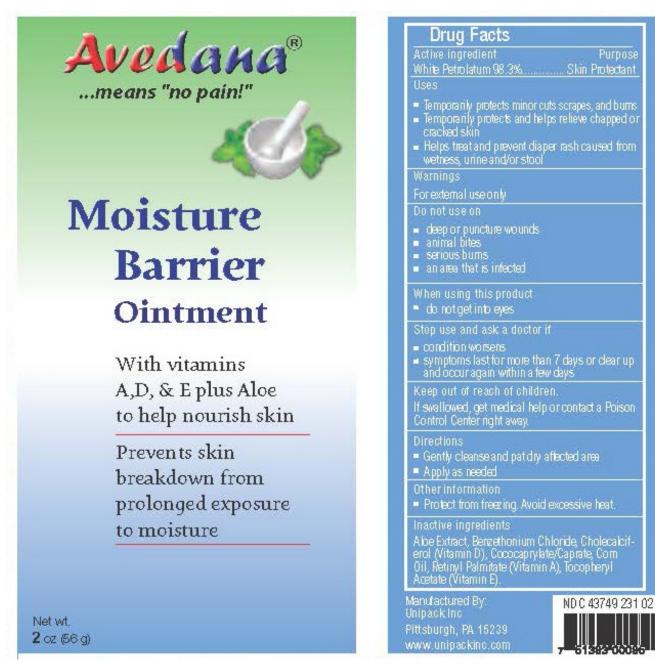
aloe extract, benzethonium chloride, cholecalciferol (vitamin D), cococaprylate / caprate, corn oil, retinyl palmitate (vitamin A), tocopheryl acetate (vitamin E).

Purpose

Other information

Protect from freezing. Avoid excessive heat.

Label





Moisture Barrier **Ointment**

With vitamins A,D, & E plus Aloe to help nourish skin

Prevents skin breakdown from prolonged exposure to moisture

Net wt 2 oz (56 g)

Drug Facts

Active ingredient Purpose White Petrolatum 98.3%.....

- Temporarily protects minor cuts scrapes, and burns
 Temporarily protects and helps relieve chapped or cracked skin
- wetness, urine and/or stool

For external use only

Do not use on

- deep or puncture wounds

- an area that is infected

When using this product

do not get into eyes.

Stop use and ask a doctor if

- symptoms last for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

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

- Gently cleanse and patidry affected area.
- Apply as needed

Other information

Protect from freezing. Avoid excessive heat.

Inactive ingredients

Aloe Extract, Berzethonium Chloride, Cholecalcif-erol (Vitamin D), Cococaprylate/Caprate, Com Oil, Retiryl Palmitate (Vitamin A), Tocopheryl

Manufactured By:

Pittsburgh, PA 15239



MOISTURE BARRIER

moisture barrier ointment ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43749-231
--------------	----------------	--------------------	---------------

TOPICAL Route of Administration

Active Ingredient/Active Moiety

8		
Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN	19U) PETROLATUM	98.3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
COCO-CAPRYLATE/CAPRATE (UNII: 8 D9 H4QU99 H)	.993 g in 100 g
BENZETHO NIUM CHLO RIDE (UNII: PH41D05744)	.004 g in 100 g
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	.5 g in 100 g
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	.1 g in 100 g
CORN OIL (UNII: 8470G57WFM)	.1 g in 100 g
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)	.002 g in 100 g
CHOLECALCIFEROL (UNII: 1C6 V77QF41)	.001 g in 100 g

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:43749-231-02	56 g in 1 TUBE; Type 0: Not a Combination Product	02/03/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/03/2018	

Labeler - Unipack, Inc. (009248480)

Establishment			
Name	Address	ID/FEI	Business Operations
Unipack, Inc.		009248480	manufacture(43749-231)

Revised: 5/2018 Unipack, Inc.