

SOOTHE AND COOL MOISTURE BARRIER- petrolatum ointment
Medline Industries, LP

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.

071 Soothe & Cool Moisture Barrier Ointment

Active ingredient

White Petrolatum 98.3%

Purpose

Skin Protectant

Uses

- temporarily protects minor: cuts, scrapes, burns
- temporarily protects and helps relieve chapped or cracked skin
- helps treat and prevent diaper rash. Protects minor skin irritation associated with diaper rash and helps seal out wetness

Warnings

For external use only.

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

When using this product

- do not get into eyes

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days, or clears up and occurs again within a few days

Keep out of reach of children.

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

Directions

- for skin protection: apply as needed
- for diaper rash: change wet and soiled diapers promptly, cleanse the diaper area, and

allow to dry. Apply product liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Inactive ingredients

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

Manufacturing Information

Manufactured for:

Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

www.medline.com

1-800-MEDLINE (633-5463)

REF: MSC095380

V1 RK21UPK

Package Label



NDC: 53329-071-14

SOOTHE & COOL[®] BARRIER

MOISTURE BARRIER OINTMENT

- + Vitamins A, D & E
- + With Aloe
- + Protects minor skin irritation associated with diaper rash and helps seal out wetness



NET WT.
2 OZ
(56 g)

REF MSC095380



Drug Facts

Active Ingredient **Purpose**
White Petrolatum 98.3% Skin Protectant

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■ for skin protection: apply as needed. ■ for diaper rash: change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry. Apply product liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other Information

■ Protect from freezing. Avoid excessive heat.

Inactive Ingredients: Aloe Extract, Benzethonium Chloride, Cholecalciferol (Vitamin D), Cococaprylate/ Caprate, Corn Oil, Retinyl Palmitate (Vitamin A), Tocopheryl Acetate (Vitamin E)

REF MSC095380

www.medline.com

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SOOTHE AND COOL MOISTURE BARRIER

petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	98.3 g in 100 g
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Inactive Ingredients

Ingredient Name	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
CORN OIL (UNII: 8470G57WFM)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
ALOE (UNII: V5VD430YW9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-071-14	56 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2019	
2	NDC:53329-071-15	198 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2019	
3	NDC:53329-071-96	144 in 1 BOX	03/01/2006	
3	NDC:53329-071-16	5 g in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:53329-071-16	5 g in 1 PACKET; Type 0: Not a Combination Product	03/01/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	03/01/2006	

Labeler - Medline Industries, LP (025460908)

Registrant - Medline Industries, LP (025460908)

Revised: 8/2023

Medline Industries, LP