

SOOTHE AND COOL FREE MEDSEPTIC SKIN PROTECTANT- lanolin 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.

042 Soothe & Cool Medseptic Skin Protectant

Active ingredient

Lanolin, USP 50%

Purpose

Skin protectant

Uses

- helps to relieve minor skin irritations caused by wetness, urine and/or stool
- temporarily protects chapped or cracked skin.
- helps seal out wetness

Warnings

For external use only

When using this product

- do not get into eyes
- do not use on deep or puncture wounds, animal bites, and serious burns

Stop use and ask a doctor if

- condition worsens or symptoms persist 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 right away.

Directions

- gently cleanse and dry affected area
- apply liberally to affected area as needed.

Other information

Inactive ingredients

8-hydroxyquinoline, aloe barbadensis leaf juice, beeswax, cholecalciferol, disodium EDTA, methylparaben, petrolatum, propylparaben, retinyl palmitate, sodium borate, sorbitan sesquioleate, tocopherol, water, zeamays (corn) oil

Manufacturing Information

Manufactured for: Medline Industries, Inc.

Three Lakes Drive, Northfield, IL 60093 USA

Manufactured in USA of domestic and foreign components

www.medline.com

1-800-MEDLINE

REF: MSC095650

RA17SFZ

Package Label

Drug Facts

Active ingredient	Purpose
Lanolin, USP 50%	Skin Protectant

Uses ■ Helps to relieve minor skin irritations caused by wetness, urine and/or stool.
■ Temporarily protects chapped or cracked skin.
■ Helps seal out wetness.

Warnings

■ **For external use only.** ■ Do not get into eyes.
■ **Do not use on deep or puncture wounds, animal bites, and serious burns.** ■ Stop use and ask a doctor if condition worsens or symptoms last 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.

Directions ■ Gently cleanse and dry affected area.
■ Apply liberally to affected area as needed.

Other information ■ Protect from freezing.
■ Avoid excessive heat.

Inactive ingredients:

8-Hydroxyquinoline, Aloe Barbadensis Leaf Juice, Beeswax, Cholecalciferol, Disodium EDTA, Methylparaben, Petrolatum, Propylparaben, Retinyl Palmitate, Sodium Borate, Sorbitan Sesquileate, Tocopherol, Water (Purified), Zea Mays (Corn) Oil.

REF MSC095650

www.medline.com

Manufactured in USA of domestic and foreign components for Medline Industries, Inc., Northfield, IL 60093 USA. **1-800-MEDLINE** RA17SFZ



LOT



Date of
Manufacture



NDC: 53329-042-77

SOOTHE & COOL[®]

MEDSEPTIC

SKIN PROTECTANT

- + Helps prevent incontinence related skin irritations
- + Treats chapped or cracked skin, and minor burns



Net Wt:
0.5 oz (14.17 g)

SOOTHE AND COOL FREE MEDSEPTIC SKIN PROTECTANT

lanolin ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-042
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	500 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
OXYQUINOLINE (UNII: 5UTX5635HP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
WATER (UNII: 059QF0KO0R)	
CORN OIL (UNII: 8470G57WFM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-042-44	113 g in 1 JAR; Type 0: Not a Combination Product	01/01/2007	
2	NDC:53329-042-77	14 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	01/01/2007	

Labeler - Medline Industries, LP (025460908)**Registrant** - Medline Industries, LP (025460908)