

SOOTHE AND COOL INZO BARRIER- dimethicone cream
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.

777 Soothe and Cool INZO Barrier

Active ingredient

Dimethicone 5%

Purpose

Skin Protectant

Uses

Temporarily protects

- and helps relieve chapped or cracked skin
- minor cuts, scrapes, and burns

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
- 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

Inactive ingredients

Benzethonium Chloride, Cetyl Alcohol, Chloroxylenol, Cholecalciferol, Glyceryl Stearate, Lanolin, Quaternium-15, Retinyl Palmitate, Sodium Cocoyl Isethionate, Sorbitol, Tocopheryl Acetate, Water, Zinc Oxide.

Package/Label Principal Display Panel

NDC: 53329-777-04

REF MSC095420

Soothe & Cool[®]

Protect

INZO[®]
Barrier Cream
with 5% dimethicone

Invisible Skin Protectant
Contains Zinc Oxide
Extra-Strength

REF MSC095420

MEDLINE

4 Fl. Oz. (118.29 mL)

Drug Facts	
Active Ingredient	Purpose
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Uses Temporarily protects ■ and helps relieve chapped or cracked skin ■ minor cuts, scrapes and burns	
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 ■ 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.	
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1-800-MEDLINE PH10CTR

NDC: 53329-777-04

Soothe & Cool

Protect

INZO Barrier Cream

with 5% dimethicone

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SOOTHE AND COOL INZO BARRIER

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-777
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LANOLIN (UNII: 7EV65EAW6H)	
QUATERNIUM-15 (UNII: E40U03LEM0)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SORBITOL (UNII: 506T60A25R)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
WATER (UNII: 059QF0KO0R)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-777-04	118 mL in 1 TUBE; Type 0: Not a Combination Product	04/01/2009	12/31/2017
2	NDC:53329-777-96	144 in 1 BOX	04/01/2009	12/31/2017
2		8 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph final	part347	04/01/2009	

Labeler - Medline Industries, LP (025460908)

Revised: 11/2021

Medline Industries, LP