# 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.

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#### 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**

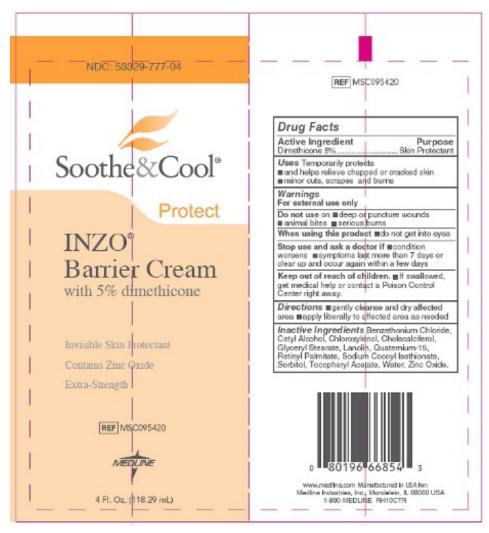
• gently cleanse and dry affected area

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

Soothe & Cool

**Protect** 

**INZO Barrier Cream** 

with 5% dimethicone

Invisible Skin Protectant

Contains Zinc Oxide

Extra-Strength

#### Medline

4 Fl. Oz. (118.29 mL)

### **SOOTHE AND COOL INZO BARRIER**

dimethicone cream

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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 (LINII: 02BLI3N3V1O) (DIMETHICONE - LINII:02BLI3N3V1O)	DIMETHICONE	5 a in 100 ml

DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10) 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: 2300U9XXE4)	
LANOLIN (UNII: 7EV65EAW6H)	
QUATERNIUM-15 (UNII: E40U03LEM0)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SORBITOL (UNII: 506T60A25R)	
.ALPHATOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
WATER (UNII: 059QF0KO0R)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

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#	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

Category	Citation	Date	Date
OTC monograph final	part347	04/01/2009	

# Labeler - Medline Industries, LP (025460908)

Revised: 11/2021 Medline Industries, LP